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MEDICAID PRESCRIPTION DRUG PRICING

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH
FOR FAMILIES AND THE UNINSURED

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

ON

S. 2605 and S. 3029

SEPTEMBER 17, 1990

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MEDICAID PRESCRIPTION DRUG PRICING

MONDAY, SEPTEMBER 17, 1990

U.S. SENATE,
SUBCOMMITTEE ON HEALTH FOR FAMILIES
AND THE UNINSURED,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:04 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Donald W. Riegle, Jr. (chairman of the subcommittee) presiding.

Also present: Senators Bradley, Pryor, Breaux, and Chafee.

[The press release announcing the hearing follows:]

[Press Release No. H–50, August 17, 1990]

HEARING PLANNED ON MEDICAID DRUG REIMBURSEMENT PROPOSALS; ACCESS TO AFFORDABLE, HIGH QUALITY CARE TO BE EXAMINED

WASHINGTON, D.C.—Senator Donald W. Riegle, Jr., (D., Michigan), Chairman of the Senate Finance Subcommittee on Health for Families and the Uninsured, on Friday announced a hearing on modifying Medicaid's drug reimbursement program.

The hearing will be *Monday, September 17, 1990 at 10 a.m.* in Room SD–215 of the Dirksen Senate Office Building.

"This hearing will examine proposals to modify drug reimbursement in the Medicaid program in order to improve access to affordable high quality care," Riegle said.

"I'm concerned about the impact that rising health care costs, including the price of drugs, may have on access to affordable, life-sustaining medications to Medicaid recipients. I am looking forward to hearing proposals from Senator Pryor, the Administration and a number of pharmaceutical companies," Riegle said.

OPENING STATEMENT OF HON. DONALD W. RIEGLE, JR., A U.S. SENATOR FROM MICHIGAN, CHAIRMAN OF THE SUBCOMMITTEE

Senator RIEGLE. The Committee will come to order. Let me welcome all those in attendance this morning, and my colleague Senator Pryor. Let me indicate that Senator Hatch, who is the first person to question Judge Souter this morning in the Judiciary Committee, wants to be present and will be present but must attend to that assignment first and then will be joining us here. We will have him testify at the earliest moment we can when he is able to join us.

Let me welcome all of those others in attendance, and in particular our witnesses. We have a distinguished panel of witnesses today. There is great interest in this hearing as the attendance in the room and the long line of persons standing down the hallway wanting to come in indicates.

This morning the Committee will be hearing testimony on Medicaid Drug Reimbursement Proposals. I am holding this hearing today at the specific request of Senator Bentsen, who is Chairman of the Finance Committee, who himself is otherwise involved at the moment with the Budget Summit out at Andrews Air Force Base.

The Finance Subcommittee on Health for Families and the Uninsured has jurisdiction over the Medicaid program. We have had many requests to testify today and we have tried to accommodate as many people as possible. At this point, we have 14 witnesses scheduled which is a very substantial number for a given hearing. I want to also say that all other statements from any interested party is welcome. They will be carefully considered by the Subcommittee and full Committee, and we will make those a part of the official record of this hearing.

I also want to say that the National Governor's Association and the American Public Welfare Association were not able to testify today.

[The comments of the National Governor's Association appears in the appendix.]

Senator RIEGLE. This hearing will examine the merits of proposals developed by Senator Pryor, by other members of Congress, the administration, and pharmaceutical companies as well as explore current issues related to the cost of drugs. Like everyone else, I am concerned about the impact that rising health care costs, including the price of drugs, may have on the access to affordable life-sustaining medications for Medicaid recipients.

A bi-partisan group of Senators from this Committee and the Labor Committee are working to develop a comprehensive proposal to ensure access to health care and to control rising health care costs. From my vantage point, access to affordable high quality health care for all Americans, for every citizen in our society, is a top priority and I think it ought to be for the country. I am very hopeful that we can persuade the President to make that the centerpiece of a domestic agenda program for the coming year.

Like all health care programs, State Medicaid programs are under tremendous financial pressure as a result of spiraling health care costs. In 1988, Medicaid paid $3.3 billion for prescription drugs, and that was the third highest category within all Medicaid spending. That amount was more than the amount that was expended for physician care payments. Drug price inflation, rather than increased use, accounts for virtually all of the increased Medicaid drug expenditures. And looking ahead in 1990, which of course we are in the midst of but have not completed, Medicaid prescription drug costs are expected to total some $4.4 billion for this year.

Although I am not a co-sponsor of either of Senator Pryor's bills I believe we all recognize the necessity of supporting meaningful cost containment efforts. In fact, drug manufacturers have been active in developing proposals themselves. Also, Medicaid drug reimbursement proposals have been raised by the Office of Management and Budget. They have apparently been circulating proposals during the Budget Summit negotiations.

It is important that we seriously address the issue of cost containment. We need to be sure that our Government spending is cost effective and that it includes developing a workable drug cost containment plan. But at the same time—and I underscore this—

we must not compromise the quality of health care provided to our low income citizens in an effort to control costs. I know my colleagues share that view. And very specifically, I know Senator Pryor feels as strongly about that as I do.

So I would not support, and I am confident a majority of my colleagues would not support, proposals that are found in the end to result in lower quality of health care for any American. That is clearly not the objective and it is something that we will work and assure that it is not an unintended consequence.

Before introducing our witnesses, let me now call on Senator Pryor.

OPENING STATEMENT OF HON. DAVID PRYOR, A U.S. SENATOR FROM ARKANSAS

Senator PRYOR. Mr. Chairman, I want to thank you for holding the hearing. I can truly say that this has been one of those issues that I have been concerned with for some time. I know you have, all the members of this Committee have. I think it is time we now faced it squarely and fairly, and truly tried to find a solution to this mounting problem.

I think, Mr. Chairman, that the Medicaid program—that is the program serving the poorest of the poor—is getting a second-class deal from our nation's drug manufacturers. Year in and year out the drug companies have refused to give our $5 billion prescription drug program the 40 to 70 percent discounts on drugs that they routinely offer to other smaller purchasers of their products. By not having access to these discounts, Mr. Chairman, the Medicaid program has shouldered the unyielding and entire weight of prescription drug price inflation.

Our constituents tell us every time they get the chance this is no light burden. In fact, the chart I brought with me demonstrates over the past 10 years that while consumer prices have increased 58 percent, prescription drug prices have increased by a staggering 152 percent. That demonstrates a staggering rate of inflation which is unyielding and has resulted in unfair prices and unfair profits. The price increases have forced States to slash the Medicaid recipient's benefits, and reimbursements to pharmacies and other health care providers

In essence, the drug manufacturers are holding the States and the Federal Government hostage to their price increases. To liberate the States from this unbearable situation, I have proposed two legislative approaches which will assure fair prices and guarantee substantial savings for Medicaid.

The first bill, S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990, saves money by requiring manufacturers to bargain over the value of their drugs. By the drug manufacturers reaction to my legislation, you might think that bargaining over the value of their drugs was something they had never done before. They claim this bill will establish second class medicine for Medicaid patients. In fact, the manufacturers today engage in this type of bargaining day in and day out with the nation's best hospitals and HMOs. In fact, one HMO, Kaiser, serves over 400 Senate employees on an in-patient and out-patient basis. No one is saying that Kaiser is providing second class medicine, are they?

I would like to submit an Aging Committee staff briefing for the record that documents how negotiating systems established in S. 2605 are used throughout the country by such respected institutions as the Harvard Community Health Plan, the Cleveland Clinic, and, yes, the Mayo Clinic. I think no one in here would say that the Mayo Clinic provides second-class health care.

[The information appears in the appendix.]

Senator PRYOR. The drug industry, by their own admission, is afraid of enactment of S. 2605. They are afraid that private insurers might use the same approach. And very recently, in an attempt to make certain this does not happen, a number of the drug companies shocked the industry by offering their own proposals that eliminate the negotiating methods outlined in S. 2605. And in most of these plans the manufacturers promise to give Medicaid their best or something close to their best prices.

I have commended, Mr. Chairman, publicly and privately, those select companies that have developed their own plans for at least being sensitive and trying. Unfortunately, CBO and OMB do not cost out promises, and they have informed me that it is highly unlikely that the proposals by the drug companies will produce significant savings.

In response to the industry alternatives, I introduced a second bill last Wednesday, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act—S. 3029. It builds on the plans that the manufacturers have proposed. The main difference between my plan and their plans is, by indexing the manufacturer's current best price to the rate of inflation, my plan assures significant savings for Medicaid. The plan has been endorsed by Families USA, the Children's Defense Fund, the National Council of Senior Citizens, the AARP, the American Cancer Society, the National Association of Retail Druggists, and the American Pharmaceutical Association.

Mr. Chairman, we have all seen an extraordinary, well-financed campaign by PMA and its member drug companies to roll onto Capitol Hill in an attempt to defeat both of these pieces of legislation. I do not mind a good fight. In fact, I enjoy a good fight, Mr. Chairman. But it does sadden me to know that the same vulernable people, the poorest of the poor, paying such high drug prices already, will be forced to pay even higher drug prices to underwrite this very, very extensive lobbying campaign.

Mr. Chairman, it would have been less expensive for the pharmaceutical manufacturers to have endorsed my bills and save all the money that they are spending now on lobbying against my legislation. Despite the industry's very intense campaign, I believe we are on the verge of enacting a Federal Medicaid drug cost reduction law.

Now why is that? We are in an era of great fiscal and social needs. A poverty program for the poor should not be forced to pay unjustifiably high and inflated prices. The fact is, we spend well over half of the Medicaid drug budget on expensive brand-name drug products. In some States, it is as high as 90 percent. If Medicaid received discounts, as HMOs, DVA, and others receive, just 20 percent or 30 percent, we would save between $200–$300 million, maybe $400 million a year. It might not mean much to the drug industry, but it would make a lot of difference to the Medicaid programs and the poor people it serves.

Some people within the industry, Mr. Chairman, argue I should not be critical of profit margins of the industry. They say they already have given their fair share. I find this astonishing. Year after year the brand name prescription drug industry leads all industries in record profits across all categories. Here is a chart, Mr. Chairman, that demonstrates that of all Fortune 500 companies, the pharmaceutical manufacturers are the most profitable year after year.

Mr. Chairman some will say that these profits are needed to fund the tremendous cost of research and develop the industry has to bear.

Mr. Chairman, I say that these inflated prices go to pay for the tremendous cost of marketing drugs, which have little or no therapeutic advance over drugs in the market. Some recently released information concluded that for every $1 that the drug manufacturers are investing in research and development, $3.50 is spent on marketing and advertising.

Mr. Chairman, in an intent to induce the drug manufacturers to come forward with a cure for cancer, to come forward with a cure for Alzheimer and Parkinson and the dreaded disease of our generation, AIDS, the Finance Committee has provided tax credits, and tax breaks. In addition, we give them a patent that lasts for several years, essentially granting a monopoly. Many of the companies then go to Puerto Rico to manufacture the drugs where there are no State or Federal income taxes paid.

Finally, Mr. Chairman, let me say that in this era of fiscal constraints, we might need to reduce some entitlement programs. There is no justifiable way, there is no justifiable reason, that we can ask Medicare beneficiaries, physicians, hospitals, or pharmacists to do more while we leave the very, very profitable drug companies untouched and unscathed.

And, Mr. Chairman, it is going to take Federal legislation. While I once again applaud several of the companies, like Merck, which have come forward with some ideas, we cannot cost out those estimates, nor can we say that 2 years from now that the same people running Merck are going to still be at Merck. We have to have Federal legislation. It may not be a very good alternative, but it is the only alternative we have.

I look forward to hearing our witnesses today, Mr. Chairman. And I look forward as they come forward to tell us what they would do about these tremendous prescription drugs costs increases in the Medicaid program. I have offered to communicate with the drug companies and to negotiate; and I have laid two plans on the table. Now I think it is time that the burden should be laid on them to lay their plans on the table. Thank you, Mr. Chairman.

Senator RIEGLE. Thank you, Senator Pryor. We will make those charts a part of the record with your statement.

[The prepared statement of Senator Pryor and charts appear in the appendix.]

Senator RIEGLE. I must say, I move to comment based on the forcefulness and power of your presentation that my mind goes back 24 years to when we were serving together in the House of Representatives, and the great concern you had about what was going on in the lives of senior citizens at that time. Our country was paying very little attention to it. I remember you started out with an idea that we ought to set up a Committee to look at the problems that were affecting older people in our country; and the old bulls that were running the House of Representatives at the time did not much like the idea of creating a committee to look at that problem.

I remember that you were able to get volunteers to come forward and actually set up a house trailer on the House side of the Capitol to begin to work on the problems of senior citizens and the elderly, including their access to health care and the medicines that they need. So this is not a new interest of yours. This is an interest that stretches back at least two and a half decades.

Senator PRYOR. Yes, Mr. Chairman. Thank you.

Senator RIEGLE. I think it is important that that be known.

Senator Breaux?

Senator BREAUX. Just very briefly, Mr. Chairman. Was that 4 years ago? Boy, time flies.

Senator PRYOR. You were in primary kindergarten. [Laughter.]

Senator BREAUX. Thank you very much. I was over there as a staff person though.

OPENING STATEMENT OF HON. JOHN BREAUX, A U.S. SENATOR FROM LOUISIANA

Senator BREAUX. Thank you, Mr. Chairman. I just think it is very important to note that these hearings are incredibly timely as our budget negotiators are meeting at Andrews and other places. I think everybody knows that there are going to be some instructions in the area of Medicaid as well as probably Medicare and other areas. I think it is so important that we try and take the time now to structure something that is going to meet their requirements in a fair manner.

Second, I would just say to our colleague, Senator Pryor from Arkansas, thank you for bringing this to our attention. Your suggestions, I think are incredibly helpful. I think you have spent a great deal of time, as the Chairman has indicated, trying to work out something that is fair and something that is workable for the American people. I applaud your efforts. I want to be a part of them and to do it in a manner that is fair to everyone, including the manufacturers. But also to ensure that we can do a better job of delivering the services to the people than I think we have been doing in the past, and commend you for your effort.

Senator RIEGLE. Thank you, Senator Breaux.

Senator Bradley?

OPENING STATEMENT OF HON. BILL BRADLEY, A U.S. SENATOR FROM NEW JERSEY

Senator BRADLEY. Mr. Chairman, let me thank you very much for the hearing and also let me thank Senator Pryor for all the time that he has invested in this issue.

The hearing today comes at a time when the buying power of the health care dollar has been severely eroded by health care inflation and by an ever-expanding array of expensive technologies that have enormous potential for improving the health and function of our people. But all this comes at a very high price.

Let me say that there are pressing needs in this country. There are pressing needs for problems that could be addressed by Medicaid. But we do need dollars to address the problems of prenatal care and early childhood health care. These dollars will largely come from Medicaid expenditures. So the pressure is to seek to save as much as we can so that we can cover more people who are in need of adequate health care.

At the same time, Mr. Chairman, let me say that the pharmaceutical industry has a long track record of successful research, that it created products that have made life better for millions of people in this country and all around the world. This is an industry that when it makes a successful break through, infections are defeated—breakthrough drugs can unclog arteries, and save countless ulcer sufferers from the surgeon's knife. It is a very successful industry, that is true. A major leader internationally, that is true. One of the American industries that continues to be a major leader internationally. Something we should take some pride in.

Senator Pryor has in the Aging Committee held hearings on his proposal. There are two proposals before the Finance Committee today. One of those is, in my view, better than the other. As the Senator knows, I had some problems with his first approach; and I think that his second approach is better. It is based on ensuring that Medicaid recipients have access to the best price for pharmaceutical drugs. As he says, it is patterned in part on some of the innovations that have come forward from some of the drug companies.

I think that this approach offers the promise of significant savings for the Medicaid program while ensuring that even new innovative drugs will be discounted and access to these drugs assured. However, let me share with you some—Well, let me share with you at this point just two concerns I have about the approach as I understand it now.

It seems to me that what it might become is a rigid system of price controls that could very well introduce some serious market distortions. Now, you know, price controls always seem like a good idea until you get into them for a couple of years. Then you find some major problems. I would hope that the witnesses today might explore specifically what problems might arise if we add the rigid system of price controls on the drugs in question. This is not an insignificant question and it is one that I think the witnesses today will be uniquely qualified to address.

But another aspect of the bill that troubles me is this whole issue of prior authorization. It troubles me because it would require practitioners to obtain prior approval, meaning doctors, usually by phone for specific medication before a prescription can be filled. You will also need a backup with the pharmacist to verify that this approval is in place.

I understand why we got to this point, but let's think about how it might work. Imagine a busy physician with a room full of patients waiting outside the office. Now this is a physician who is treating Medicaid patients for a notoriously low fee and the room is full. A patient comes in and is sick. It may be emphysema; it may be a variety of other illnesses, and requires, because of the physician's knowledge, a new state-of-the-art drug, along with a combination of other prescriptions which are all mixed in order to give the patient the care that he or she needs. Imagine now at this point when the doctor decides what he or she wants to prescribe the doctor now has to get on the phone. The physician has to call some bureaucrat for prior approval to give the medicine that the doctor knows and believes, based upon medical knowledge, will do the job.

Well what will happen from time to time is that it will be simpler simply to write for a less effective alternative. You will not use the latest state-of-the-art drug that might do the job. You will write for the less effective alternative so you are not bothered with the bureaucracy checking you.

Or take the circumstance, because it is a double check, where the patient obtains the prescription from a physician who neglected to call for prior approval. He takes it down to the pharmacist and says, "Here is my prescription. The doctors says this will solve and help me get better." The pharmacist says, "Well I am sorry that cannot be filled. It cannot be paid for."

Well he calls the physician. Will he call? The physician did not call in the first place. So the likelihood is that the sick individual will not get the prescription. So I would hope, Mr. Chairman, that we would look carefully at the proposal. While it is, I think, an improvement over the first proposal, I still think there are areas that need to be explored. Indeed, we are here to explore ways to save Medicaid money in a way that will not hamper a successful innovative industry's ability to continue to find ways to improve the health of our citizens.

I might say that I believe we have come a long way. A year ago it was not even possible to get all the principals in the same room to discuss an approach to the problem. Today we have before us a potentially realistic approach that could be refined and modified in ways that might meet everybody's requirements.

I hope that the discussions will be conducted in good faith and I am confident both the industry and the Congress can arrive at a proposal that would best serve the nation's poor. But we should not treat lightly the possibility that there are other diseases out there waiting to be cured for which research is essential. We should not treat that lightly. We should not decide, for whatever reason, that we are going to limit our possibility, not only to continue the lead in an economic sector internationally, but to improve the health of millions of people in this country and around the world.

Mr. Chairman, I thank you.

Senator RIEGLE. Thank you, Senator Bradley.

Before we go to the first witness, Senator Pryor, did you have any other comments you wanted to add before I go on?

Senator PRYOR. Mr. Chairman, I think I have decided on a course of action today. I know that there are going to be many concerns, as expressed by Senator Bradley in his eloquent statement. What I am going to do is make a list of these concerns and at the end of the hearing answer each of the concerns, rather than trying to answer each one as they come. I do have, I think, a response to each of Senator Bradley's concerns that I hope will be satisfactory to him.

Thank you, Mr. Chairman.

Senator RIEGLE. Senator Pryor, we will be sure that we reserve time at the end for that.

I want to indicate again before calling on our House colleagues that Senator Hatch will be coming over from the Souter hearing at some point. And when he does I am going to make just sort of an ad hoc arrangement to accommodate his timing need and I know everyone will understand.

Let me now introduce our two House witnesses that we are pleased to have with us today—Hon. Ron Wyden, from the State of Oregon, and who is a member of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce; and with Congressman Wyden is Congressman Jim Cooper, who is also a sponsor of the Medicaid Prescription Drug Fair Access and Pricing Act, which is a companion bill to this new Pryor bill that has already been discussed this morning.

I say to our House colleagues, Cooper and Wyden, we are delighted to have you both. Mr. Wyden, why don't you begin and then we will call on Mr. Cooper.

STATEMENT OF HON. RON WYDEN, A U.S. REPRESENTATIVE FROM OREGON

Representative WYDEN. Thank you very much, Mr. Chairman.

Senator RIEGLE. Let me just say also at this point, and I apologize for interrupting you, but I am going to try to ask all people who are presenting today, and there will be a large number, to try to keep their summary comments within 5 minutes so that we can reserve the time for Q&A back and forth. We will make full statements a part of the record, but I would hope we could stay within that time limit as an accommodation to everyone who needs to be heard.

Representative WYDEN. Thank you, Mr. Chairman. I am going to start the day off right by doing that. If I could make my comments a part of the record I would appreciate it.

Mr. Chairman, and Members of the Committee, with what the drug companies have overcharged Medicaid during the last decade alone, millions of poor families could have received basic health care benefits. The fact of the matter is that no savvy cost- conscious purchaser of medicine in the private sector would be paying the prices that Medicaid is paying today.

I think it is important to understand why this is going on. The Drug industry has simply been stiffing the Medicaid program. If you are a preferred customer in the private sector, they will negotiate with you and you can hold the prices down. But when it comes to Medicaid, the Government has just handed over a blank check to the drug industry and in effect said, "You fill in the numbers."

I think all of us have said that the country cannot afford to let the drug companies gobble up scarce Government dollars. What I would like to do for a moment is just touch on some of the arguments that the industry has made and give you our response.

First, it does not seem to me to be setting up a system of price controls when you do nothing more than what the drug companies are letting the big private buyers do in the private sector. The big health maintenance organizations and the big private sector programs are already doing just what H.R. 5589 calls for and nobody has said that that is a system of price controls.

Second, the industry says that this will damage research and development. I strongly support tax credits for the purpose of encouraging research and development. But I particularly, Mr. Chairman, wanted to submit for the record a memo done by Kidder, Peabody, the important investment firm, done in April of this year which says that the impact of the original Pryor bill, S. 2605, and I quote, "would be immaterial for the industry." So this notion that somehow this is going to damage the competitiveness of the companies is directly contradicted by this recent memo done by Kidder, Peabody.

The last point that I would want to mention with respect to the mechanics of the bill deals with this question of access for poor people. The only thing that this legislation does is that it expands access. It calls for open formularies. In an April document done by the PMA at least 19 States have sharply restricted formularies and the PMA says a number of others have additional restrictions. Our bill calls for "open formularies." That is expanding access.

Second, our legislation makes a number of changes from the original version of the Pryor bill, S. 2605. There is no therapeutic substitution, so a doctor can control the medicine that the consumer will get. There is no therapeutic equivalence, so you do not have some kind of Committee making decisions about preferring one drug or another.

And finally, with respect to the important point that Senator Bradley has made regarding prior approval, the only thing that our legislation does is to make prior approval less restrictive than it is today. In a lot of States in this country you do not even have people answering the telephone when it comes to prior approval. You have nothing there at all to make it possible to get the drugs out to the low-income people. Our legislation—and we do not say for a second that it is perfect with respect to prior approval—goes a significant step further than we are at today with respect to access by making sure that there is somebody there around the clock for instant response. That is expanding access. So I think those are important points. They reflect the differences.

Unfortunately in the Health and Environment Subcommittee on Friday we heard that the PMA, the group representing the industry, is still opposed to the second bill. I think more than anything I come today because I think Senator Pryor—and we have been very pleased to work with him on this from the beginning—Senator Pryor, and I, and Mr. Cooper, have tried to walk the extra mile to accommodate legitimate industry concerns. We are still willing to. But I just think what the industry hopes to do is in effect push this aside, say that their private sector programs are going to take care of it, and somehow keep this gravy train going. I think that is unacceptable.

I am very pleased to have a chance to be here with my colleague, Senator Pryor, who of course, has sparked this; and I think has done a tremendous job. And ultimately, what we have to face is that no savvy purchaser in the private sector would be paying what Medicaid is paying today and it is time to bring it to an end.

I thank you.

Senator RIEGLE. Thank you very much, Congressman Wyden.

I want to go to Congressman Cooper from Tennessee. But before I do, Senator Hatch has joined us and if I may—I have explained that you are in the middle of the Souter hearings and were the first one up to question and must get back there. So at this time, we would be pleased to hear from Senator Hatch.

Let me just say that Senator Hatch, of course, from Utah, is the ranking minority member of the Committee on Labor and Human Resources; and I think probably is as active on health issues and matters relating to people getting their health and medical needs met as anybody in the Senate. So we are very much pleased to have his testimony.

STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Senator HATCH. Thank you very much, Mr. Chairman. I appreciate your kind remarks. I am sorry to be a little bit late, but I was the first off to question Judge Souter in the Judiciary Committee hearings this morning, and I shortened those so I could get in here.

I appreciate the opportunity to appear before the Finance Committee.

Senator RIEGLE. Can you give us a report as to what he said? [Laughter.]

Senator HATCH. You do not want to hear. [Laughter.]

Actually, he was so embrassive in his answers—he was so comprehensive—that I only asked two questions.

Senator RIEGLE. I see.

Senator HATCH. But he was magnificent in his answers.

I do appreciate this opportunity to appear before the Committee to give you my perspective on various proposals relating to Medicaid prescription drug costs. For many years, as you know, I have followed the issues of prescription pricing and the development of new therapeutic products.

In 1984, I was privileged to be a part of one of the most significant efforts in recent history to obtain lower prescription drug prices for the American people. In this law, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act cleared away many of the legal and regulatory road blocks of the marketing of low-priced generic drugs.

A handful of bad actors in some generic pharmaceutical companies have created some temporary difficulties for the generic industry. Many corrections have been made administratively at FDA;

and Senator Kennedy and I are working on additional legislation to provide the tools the FDA needs, so that such a scandal will not occur again.

I am satisfied that in the long run the generic drug program will continue to help the American people obtain low-cost pharmaceutical products. The so-called Hatch-Waxman Act has important bearing on this hearing today because it was developed to cut the cost of drugs without undercutting innovation. It provided consumers access to lower cost drugs that were bioequivalent to the pioneer drug once the drug was off patent. It maintained incentives for pharmaceutical companies so that they could continue their investment in research and development that ultimately led to better drug therapies for Americans. And the consumers are the winners under that bill.

They continue to benefit from important new break throughs in drug therapies and from access to lower priced drugs through increased competition in the marketplace. Patents on more than 70 new drugs, representing $5.5 billion in sales in the year 1985 alone—not new drugs but existing drugs—have expired since 1984. Because the market's share of name brand drugs has reduced by upwards of 50 percent within 2 years of when patents expire, research based companies have contributed significantly to lower health care costs.

An independent drug analyst recently noted that brand named drugs with sales totaling about $10 billion are scheduled to go off patent between 1991 and 1995, which means increased competition is helping to reduce drug prices.

Let me just show you this one chart. Within 2 years, following the expiration of the patent, the pioneer drug commands only 51 percent of the market place—and competitive forces begin to reduce the cost of the drug. The Drug Price Competition Act of 1984 is working well as an effective cost control strategy. They started off with a sole source drug and within 1 year it is down to 65 percent of the cost; and within 2 years 51 percent. It has really been an impressive bill and has done an awful lot of good for consumers, having saved billions of dollars thus far.

As a matter of fact, virtually every State has implemented mandatory generic substitution programs that have saved Medicaid and other taxpayer-financed pharmaceutical assistance programs billions of dollars since 1984. Additionally, a large percent of Medicaid expenditures are for generic drugs, rather than those that are considered sole source pharmaceuticals.

Currently, Medicaid expenditures for generic drugs account for almost one-half of the total prescription drug expenditures. This total amounts to a substantial savings in the Medicaid program, and perhaps we should consider a mechanism for scoring expected savings because there are savings because of Hatch-Waxman. However, such generic substitutions should not be confused with therapeutic substitution that I will discuss later.

As ranking minority member of the Senate Committee on Labor and Human Resources, I have spent a considerable amount of time reviewing the drug development process. For a new drug to be reviewed and approved by the FDA the manufacturer must produce a truckload of information concerning the composition of the drug, the results of clinical trials, and everything else to ensure that the drug is safe and effective for the treatment for which it was created.

The FDA regulations are necessary, but the process is costly and time consuming. I might add that the FDA revitalization bill that I have been sponsoring along with a number of you as cosponsors would help to alleviate some of those costs. But right now the costs are astronomical for development of any sole source drug of any consequence.

So the research companies really have a tremendous amount of expense that simply has to be recouped if you are going to have more and more innovative creation of pharmaceuticals in this country. Biomedical research is extremely expensive. The equipment and buildings are expensive. The salaries for top-notch scientists and regulatory experts are high. In fact, we have not hired a senior research scientist in any department of government in the last 10 years—since 1978 in the case of FDA. We cannot compete with the private sector because of the high costs and how much has to be paid for these tremendous experts.

The competition among different companies and even among nations is extremely intense and very difficult. The cost of developing a new drug has been estimated to be between $125 million and $231 million, and it is rising every year. So we need revitalization, but we also need to recognize that these companies take tremendous risks to develop a new drug.

In many instances such costs can never be fully recouped. For instance, for every ten drugs entering the market only three of them will ever recapture their development costs. Furthermore, for every compound that is commercialized, some 4,000 are abandoned in research. That has to be factored in here.

Drug prices reflect these and other business costs and risks. The competition among R&D companies is tremendously intense. Any proposal that artificially caps charges may harm the incentive to develop new therapies when we are on the verge of developing therapies for diseases and problems that no one thought ten years ago could be developed. That is going to dry up if we do not handle this properly.

I share the concerns of my distinguished friend from Arkansas, and others, including my colleagues here from the House, about the high costs of pharmaceuticals. But they are going to be a lot higher if we do not handle this in a free market incentive way. I urge you to reject any legislative proposal that gives legal bias to one company's approach over another's, favors one firm over another, or indirectly favors development of drugs for certain diseases at the expense of drugs that treat other diseases.

That is what is dangerous about this legislation. Many of the current recommendations are not sensitive to these issues. I agree that we must face the increasing costs of medical care and the expanding Medicaid budget woes. Medicaid now provides health care for over $22 million people. Total funding for Medicaid has more than doubled over the last ten years, increasing from $23.3 billion in 1980 to $48.7 billion in 1988. It is horrendous.

This increase has been due in large part to expansion of benefits and increased utilization. And when you look at Medicaid prescription drug expenditures it is predicted that in fiscal year 1991 $5 billion will be spent. That is a lot of money.

I want to commend my good friend, Senator Pryor, for motivating Congress and the pharmaceutical industry to find ways of achieving important Medicaid drug savings. He deserves a lot of credit for that.

For the record, I believe his legislative initiatives helped provide the impetus for the negotiations that are currently underway with State Medicaid programs. I want to emphasize the importance of those discussions. Reports are that 31 States have negotiated with various pharmaceutical companies for discounted drug rates, and 10 States are on the verge of signing up. I am pleased to report that my home State of Utah is one of them.

We should encourage, not discourage, these negotiations. We ought to foster the ongoing efforts of States and manufacturers by finding a way to again score the savings they will provide the Medicaid program, because they are going to provide a lot of savings. We have learned from the Hatch-Waxman law that we can achieve real and substantial savings from market forces without distorting the delicate balance of innovation and regulation.

These same market forces have acted to provide discounts to other Government health programs such as the VA. There is no reason to believe that they could not be harnessed to provide savings to Medicaid as well. Legislatively, we should score these savings that result from negotiations or contracts.

We should not enact S. 2605, S. 3029, and other similar proposals because they not only hamper the current discussions, but also because they rely on price controls, therapeutic substitution, and/or the development of formularies. These proposals, I believe, would reduce access and undermine the quality of care available to our nation's poor and disabled, especially at a time when many of us concede that it is critical to expand and improve Medicaid.

I would strongly oppose any measure that contained therapeutic substitution. With generic substitution the consumer is guaranteed a virtually identical product to the one prescribed. With therapeutic substitution, the patient gets a different product that has a different chemical composition, a different profile, different side effects, and different indications. Such substitution is bad health care policy and is opposed by a host of health care and public policy experts.

I will give you an illustration. Here are just stacks of letters from experts who oppose this type of an approach. They are not activists or ideologies. These are top health care people in this country who really have to handle these matters.

I would ask unanimous consent that these be at least placed in the record. You may not want to print them all for the record, but at least put them in the record.

Senator Riegle. We will certainly have them as part of the record and they will be on file with the Committee. I do not know that we will reproduce them, per se, but we will certainly have them for reference.

Senator Hatch. There are plenty of them here.

Senator Riegle. And we accept them on that basis.

Senator Hatch. Okay. Thank you.

In addition, I encourage the Committee to reject proposals that would force price controls on the Medicaid program. That is precisely the wrong way to go. We need to assess the impact of such proposals on the development of new drugs and the impact on access to innovative therapeutic products for Medicaid recipients. But first, let us step back and measure the savings that current negotiations are producing and the savings realized from the Hatch-Waxman Act as more pharmaceuticals go off-patent.

In addition, if there must be Federal intervention, let it be aimed at providing manufacturers with positive incentives for providing Medicaid discounts within the current competitive market framework. If you do not do it this way, we are going to discourage incentives and innovation. This will lead to less drugs at higher costs, doing less good work, and solving less problems in our society than we have the potential of having by approaching it in a scoring way that works, in a free enterprise system that works, and in a free market economical way that works.

Thank you, Mr. Chairman.

[The prepared statement of Senator Hatch appears in the appendix.]

Senator RIEGLE. Thank you, Senator Hatch. I know this is an area that, as I said earlier, you have invested a lot of time and effort in. We appreciate the thoughtfulness of your presentation. I think we have a good discussion already underway, with more good witnesses to come.

I think at this point I am going to excuse you so that you can go back to the other hearing. Because I know that is of keen interest to you and you have an obligation there. So without objection I am going to indicate that we will not go forward with questions to you at this point unless a colleague——

Senator HATCH. I would be happy to chat with my colleagues at any time.

Senator PRYOR. Mr. Chairman?

Senator RIEGLE. Yes, Senator Pryor.

Senator PRYOR. I do not have a question for my friend and colleague, Senator Hatch, but just a statement. We will introduce this for the record.

I would certainly not like for Senator Hatch to go back to the Souter hearings without at least being very aware that the facts demonstrate without question that when a drug loses its patent after 7 years the law of economics does not work in this area for some reason. I have never gotten an explanation why—the cost of that drug to the American consumer does not in fact go down. That drug price continues to rise at the cost of 15 or 20 percent a year for unexplained reason.

The other concern that I have, and Senator Hatch may have touched on it a little bit, is that the drug companies in our country sell to the poorest of the poor in America drugs at the highest possible price—the highest possible price. They even sell to the Europeans and to other countries in the world the same drugs manufactured in this country at 54 percent less than they sell them to us for the Medicaid program.

Now I cannot understand that. This is what this hearing is about. I want to again thank Senator Hatch for his concern in this.

But I did not want the record to go unchallenged about a couple of these facts that I do think are in dispute.

Senator Hatch. I appreciate that. If I could just make one additional comment.

Senator Riegle. Senator Hatch?

Senator Hatch. The Drug Price Competition Patent Term Restoration Act was a monumental bill. I cannot begin to tell you the effort that was put into that bill. We worked day and night for a long period of time. Both sides were very, very tough throughout. It had to be a classic compromise to get it through. And audibly we did. It was literally the last bill passed in that session of Congress. I was there on the floor, and there was hardly anybody else there. It passed by voice vote. And right up to that point there were outside groups trying to stop it.

Virtually everybody acknowledges that the generic copy of these drugs once they come off-patent has been much less in cost.

Now with regard to foreign drugs being much less in cost, one reason they escalate in cost when they come into our country is because of our FDA regulations. We are much more stringent than other countries. We make it much more difficult. It takes longer than other countries. We have an FDA that handles 25 percent of all the consumer products in America and yet it is located in 23 different buildings and 7 different locations without any central data processing system. It takes 8 to 10 years to get a drug through the safety and efficacy process.

It is a very difficult, very expensive, very time consuming process that adds to the costs of American drugs. I am for changing all that. Because when an Agency that handles 25 percent of all of the American consumer products does not even have a central data processing system there is something wrong. We are hurting every consumer in America. That is probably the biggest reason why the costs are as high as they are.

This still does not negate my thesis. That is, that we should not put price controls on these matters which will stifle innovation. We should find other more innovative ways and negotiation is one of them. And the State negotiations are doing a terrific job right now, and in some cases actually reducing the prices even below some of the agencies that I think the distinguished Senator from Arkansas would like to match.

The process can work well without Government stallification. I believe that this type of legislation is either going to cause prices to go even higher in the final result or most importantly it is going to stifle innovation, then we will not have the pharmaceuticals, miracle pharmaceuticals, that we intend to have in the next 5 to 10 years, if we let this incentive process work.

Well I have taken enough of your time. But it is an important issue to you. It is to me, and I think it is to the country as a whole. The question is: Which is the better way of solving it? I do not think putting price controls on is the way to do it.

Thank you.

Senator Pryor. Thank you, Senator.

Senator Riegle. Senator Bradley has asked me if—because he must also go shortly to another commitment—if he could raise one question with Mr. Wyden.

Mr. Cooper, you have been very patient and I would hope that you would indulge that question and then we will go right to you.

Senator Bradley?

Senator BRADLEY. Ron, I was taken by your advocacy of the 24-hour, 7-day a week instantaneous prior approval. I am just concerned whether you do not think that would create an administrative nightmare, given the fact that, you know, there are 15 million Medicaid recipients. Prescriptions last year processed for them were like 200 million prescriptions. You know, even a small percentage of those might seriously create a nightmare as far as I understand the process. I mean, maybe not, but it sounds to me like the cost of trying to set up this system and man it might be bigger than you might have imagined.

Representative WYDEN. I think, Senator, what we have to do is talk about the status quo. Under the status quo there are these prior approval programs. Under the status quo in a lot of States nobody even answers the telephone. I think that what we are offering is certainly a significant step forward from the status quo.

Now I have never been wild about prior approval programs. I am not going to come in here and say otherwise. But I think that when you look at what we are talking about, which would provide instant response, as opposed to the status quo where you have a mess that does not even result in a lot of cases in somebody answering the phone, what we are offering is a significant improvement.

Now I am very happy—and I am sure Senator Pryor is—to talk about other ideas as well. I am open to suggestions. But I know on the House side this came up as part of the drug industry's overall argument that we were restricting access. And when it comes to the issue of prior approval, the only thing that our bill does is make it less restrictive than what we have got. We will listen to other proposals as well.

Senator BRADLEY. Do you think that if you could get the price you do not need prior approval?

Representative WYDEN. Well I think getting best price, you know, is the heart of the agenda. I think that given the fact that States have these programs Congress has got to face the question of whether it is then going to direct the States to get rid of it. But certainly if we lock in, you know, best price, that is another argument for junking the whole thing.

This is going to be part of the debate about where we end up ultimately on this question of streamlining procedures. We only want to contend that based on the mess we got today where people are not even answering phones the proposal in the second version of the legislation is a step forward. If we can lock in best price then we certainly have another argument for getting rid of the whole thing and it ought to be on the table.

Senator BRADLEY. Thank you.

Senator RIEGLE. Congressman Cooper, you have been very patient. We would like to have you testify now. Once we finish with this set of congressional witnesses—we have Gail Wilensky next who is waiting to speak, and then others—I am going to try to adhere to the time limits that we set out at the beginning.

We have had a good debate which lays down a foundation of the opinion and issues that are involved here. So, Mr. Cooper, we would like to hear from you now.

STATEMENT OF HON. JIM COOPER, A U.S. REPRESENTATIVE FROM TENNESSEE

Representative COOPER. I thank the Chair and Members of the Subcommittee. I am confident that one day the first shall be last and the last shall be first.

I think most Americans are shocked to learn that the U.S. Government, through the Medicaid program, is the top purchaser of prescription drugs in America and yet rarely even gets the discounts that smaller purchasers get. In fact, we taxpayers usually end up paying top dollar. In most cases, Government has not even tried to get lower prices. We have let the drug companies tell us exactly how much they would like to be paid and we have paid them with no questions asked.

The cost of this extravagance has largely been hidden, but it has been extraordinary. This unlegislated, unrecorded subsidy to the pharmaceutical industry has cost the nation's Medicaid program and thus the nation's taxpayers and poor hundreds of millions of dollars a year, according to both the congressional Budget Office and the Office of Management and Budget. This vast amount of money has not reached the poor in America primarily because the U.S. Government did not get a better deal from U.S. drug companies.

This is not to say that the U.S. pharmaceutical industry is all bad. It is far from it. It leads the world in innovation and quality. Countless lives have been saved as a result of the industry's research and product development. And being the world leader is not cheap. It takes money and lots of it.

But the drug companies have found one way of getting lots of money from the Federal Government without the need for an appropriation or even an explanation. By simply refusing to bargain with the Federal Government they have created a secret subsidy for themselves that is unfair to the taxpayers and poor of America.

I am not an enemy of the drug industry. I am open to any argument they would like to make for an aboveboard targeted subsidy for their efforts.

Mr. Chairman, the leadership of the pharmaceutical industry will be tested by the manner in which it wages this fight. Will it sink to the lowest common denominator and fight to the last breath of the last company that wants to preserve this hidden and unfair subsidy or will it be thankful for the many years the U.S. Government has paid it top dollar and instead argue for open efficient subsidies that it is prepared to defend in public and on the merits?

To be honest with you, Mr. Chairman, the first skirmishes have not been very encouraging. First of all on the second class treatment argument, the bill that we are introducing in the House, H.R. 5589, assures access to the best prescription drugs on the market for our nation's poor. As Senator Pryor noted, as good as what the Mayo Clinic offers. No one need fear the creation of a second class drug system for our nation's poor. In fact, the estimated budget savings of $2.5 billion over the next 5 years that this bill will produce should allow the Medicaid program to reach out to many more people in order to serve them better.

Senator RIEGLE. Now can I just ask you one question at this point then? I take it that what you are asserting is, that you would want to see built into your bill, or any other adaptation of a legislative vehicle that comes from this, an assurance of some form that there was no reduction in the quality or the efficacy of the drug that was used in a given person's case. You would favor and insist on some form of safeguard on that issue. Is that what I just understood you to say?

Representative COOPER. I think that is fair and I think that our recently introduced bill does just that. It opens up formularies. It guarantees access to more medications than the current system of State-by-State negotiation allows.

Senator Hatch mentioned earlier all of their negotiating now. That is wonderful. We need to remember that so often States rely on closed formularies—keep drugs off the list. That hampers medical care. Our legislation offers the best hope for open formularies so that a broad array of drugs and medications is available to the poor of this country.

So I think that our legislation already takes care of the problem. But I would be happy to work with the gentleman to make sure that access to first class medicine is available to the poor of this country.

Senator RIEGLE. If I may just say one other thing. I think the reason that is so important is that—and I think if that is the intention and that is the guideline of a sort or an iron discipline as needed—it needs to be brought up front into the discussion. Because my own experience would be that so many of the people we have on Medicaid are our walking wounded. They are the people in the country who have some of the worst problems and they have accumulated over a life time, in many cases depravation. Many have not had proper health care or the right nutrition. So their health needs in many cases are more extreme.

It just follows that they are going to need the best medicine. I mean those folks are going to need medicine that can really get the job done because their health profile is probably one that is more disadvantaged.

So I think it is very important that that policy I was hearing you enunciate be emphasized.

Representative COOPER. I could not agree with the gentleman more.

And since there is confusion on this issue between the first Pryor bill and the second Pryor bill I would suggest that the Chair consider the policy adopted by Chairman Waxman on the House side last Friday. He told witnesses that he would strike from the record any reference that they made to the first Pryor bill, S. 2605, less there be confusion about the way that this second version treats the poor. Because this second version guarantees first-class medicine for the poor.

Another common pharmaceutical industry tactic has been the parade of horribles approach. We have heard a little of that today—the critical description of State prior approval plans. I believe my colleague, Mr. Wyden, has shown very clearly that our bill in no way encourages the use of prior approval plans. In fact, our bill will improve the efficiency and operation of such plans should a State choose to have one.

Should this Committee want to go ahead and preclude a State from having a prior approval plan, personally, that would not bother me. But let me describe to you how such a plan works today in Tennessee.

It is not a bureaucratic nightmare. There are only ten drugs on the prior approval list. Only ten drugs out of tens of thousands of drugs even need a phone all to the State office. And the reason our State has such a plan is, there are some drugs that are capable of solving different health problems. For example, the drug Prozac, the anti-depressant, it is also apparently effective as a weight loss drug. But it is not cost effective to be prescribed as a weight loss drug. So our office in Tennessee tries to discourage the use of that anti-depressant being prescribed as a weight loss drug.

So in answer to Senator Bradley's question, prior approval plans do serve, in a sense, as a poor man's drug utilization review. They are a way that a State can hold costs down.

Another drug industry tactic has been not to work with Congress to improve the legislation and discourage any company that is interested in talking to us. They have tried in past months to make us figure out everything on our own. Now I am thankful they are willing to talk. But if it had not been for Senator Pryor and his efforts, they would not be willing to talk today.

We have to bear in mind that we are one nation and a 50 State solution for our Medicaid beneficiaries. It has got to be preferable to a patchwork quilt of State-by-State, generally closed formulary negotiations with drug companies that had to be dragged kicking and screaming into these talks in the first place.

Another drug industry tactic has been to make our nation's poor believe that they are better served under the current system of highest possible prices, higher than the Europeans have to pay, higher than anyone else has to pay, instead of finding a way to channel some of these savings back into the Medicaid program so that their health care can be improved.

Finally, let me mention a fact that many of our drug company efforts today are spent not on improving drugs in a real sense, but on inventing "me too" drugs that are so similar to existing drugs that they are little more than a price increase excuse. These drugs have no real therapeutic advantage. They are only one molecule or one atom different from an existing drug, but they enable the drug company to charge a big price for an allegedly new formula.

If these drugs cured more, it would be worth it. But so often it is just an excuse to cost us more. These are all tactics, Mr. Chairman, that I know this Subcommittee can see through. I feel that this Subcommittee wants the pharmaceutical industry to treat its biggest customer fairly, even if it is the Federal Government; and that the pharmaceutical industry will not be able in future months and years to be able to treat Uncle Sam like "Uncle Sucker."

I thank the Chair.

[The prepared statement of Representative Cooper appears in the appendix.]

Senator RIEGLE. Thank you, Congressman Cooper, for a very direct statement.

Congressman Wyden, did you have one other comment that you wanted to make?

Representative WYDEN. Yes. Just very quickly, Senator.

On this question of the quality of medicine that you asked my colleague. I think it is a very important one. One of the differences between the second bill and the first bill is that the second bill does not have in it therapeutic substitution. This means that the doctor can control the exact drug, the exact drug, that the doctor wants the patient to get. So if the doctor believes there is a difference in quality and it is going to relate to what the low income person gets, it is addressed this way.

I thank you.

Senator RIEGLE. Yes. It is very important that that be emphasized. Because we all know that there has been a concern that has been generated based on the initial concept that maybe that would not be the case, and that somehow poorer people would not have access to a particular formulation that in the judgment of their doctor or in themselves that they would need.

You are saying, for the record, that version two directly addresses that issue so that that ought to be clear. I mean that is what I take from your testimony.

Representative WYDEN. I think you have hit a key point. Version two does not have therapeutic substitution in it.

Senator RIEGLE. It is interesting; sometimes it sounds like everybody is in a different place on these things. It is the wonder of the American legislative system that as we talk and work to a common position.

But I just want to say one thing on a philosophic note and then I am going to yield to Senator Pryor. That is this: We have to think in terms of Team America in the United States. There are roughly 250 million of us in this country and everybody is important. The cold fact of the matter is that everybody is equally important. Sometimes we lose track of that because someone is a very famous person or a great athlete or entertainer, or a very successful business person and what have you. Somebody else that is out in society that has no notoriety can be sort of pushed off to the side.

I think if America is going to be true to its values and also going to be able to excel in this new global economy that is upon us, we have to be sure that every single person in this country has an opportunity to be able to function fully. That starts with good health. That is why we need a national health insurance system that covers everybody.

The fact that there are a million people in my State today without a penny of health insurance, and 300,000 of them are kids, I think is just a terrible commentary on the fact that the United States is not paying the right attention to our health needs in that dimension. But the same is true here.

I would not want anybody out across the countryside to think that the concerns that are being expressed are anything more than trying to get the best possible health care particularly to our low income people across this country who are the group that in many cases need it the most and have had it the least, and have had good health care denied and delayed and unavailable through much of their life time.

So I want it understood that the commitment of the inquiry here is to make sure that the poorest of the poor are not forgotten and not pushed aside, not exploited in any fashion or form, but that in fact what we are looking for is something that ensures that they have a full chance, and a fair chance, and an equal chance in terms of access to the health care and medicines that is needed to get them up to a point where we want all of our people to be.

Senator Pryor?

Senator PRYOR. Mr. Chairman, I have no questions for my colleagues from the House. But if I might just say this to the Chairman and our friend from Louisiana, Senator Breaux, if either of you ever need two strong willed, brave, and also compassionate souls in the House of Representatives to help to carry the water, these two gentlemen are the ones. They have undergone a tremendous amount of not only questioning, but to some degrees criticism. A lot of times you get an ally and they will look for the nearest exit when it gets hot. Well these fellows have not done that. They have gone right into the battle; they have been absolutely splendid in every way.

I want to sincerely thank the both of you for being such, not only good allies, but also such great friends of the Medicaid recipient. And I truly appreciate it.

Thank you.

Senator RIEGLE. Thank you very much.

Senator Breaux?

Senator BREAUX. No questions, Mr. Chairman.

Senator RIEGLE. No other questions.

Let me thank you and excuse you and call Ms. Wilensky to the table. Our fourth witness is Dr. Gail Wilensky, who was here just last week. She, I am sure, remembers very clearly as do we on the Committee. She, of course, serves as Administrator of the Health Care Financing Administration in the Department of Health and Human Services—a very important policy position in our government in this area. She is here to give us the administration's view of the Pryor legislation and on other proposals to attain savings in the Medicaid prescription drug program.

We will make your full statement a part of the record. We appreciate your patience in being here for such a long time already this morning. We would like to hear from you now.

STATEMENT OF HON. GAIL R. WILENSKY, PH.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. WILENSKY. Thank you, Mr. Chairman and Members of the Subcommittee. I am pleased to be here today to discuss the issue of Medicaid prescription drug costs. I thank the Committee for the invitation; and I also thank Senator Pryor for his unflagging effort in this area.

Like you, I am encouraged by recent indications that some pharmaceutical companies are willing to provide to Medicaid discounts similar to those given to direct providers. It is only right that the poor, elderly and disabled who are dependent on medical assistance should receive the lowest prices for needed medicine.

Despite the recent good news, we are concerned that Medicaid continues to pay substantially more for drugs than many hospitals and HMOs, other Federal agencies, such as the Department of Veterans Affairs and open-ended IPAs or PPOs. As we consider Federal changes to moderate Medicaid's payment for prescription drugs, I believe it is important to understand the market for prescription drugs in our economy.

Nearly 60 percent of all prescription drugs are paid for out-of-pocket. Medicaid, Medicare, HMOs and occasionally traditional insurance pay for the 40 percent of drugs covered by third-party payments. Two key factors complicate the market place for prescription drugs. Patents grant a 17 year monopoly to new drugs, called sole-source drugs, as to other inventions, in an effort to encourage the R&D for new product development.

Consumers rely on the decisions of physicians who write the prescription. While I believe that physicians often take into account the beneficiary's financial concerns, this process distances the payor-patient from the decision about what and how much to purchase. In Medicaid, of course, the patient pays little or nothing for the prescription. Even with these complications we must use care to protect the thriving R&D associated with prescription drugs. We must be concerned for what is one of our most internationally competitive industries.

Before I describe HCFA's efforts to develop a savings policy, let me provide salient background. After lagging behind inflation in the 1970s, manufacturers' drug prices have increased over the past decade at three times the rate of general inflation. We estimate that expenditures for Medicaid prescription drugs will be $4.4 billion in fiscal year 1990 and $8.2 billion by fiscal year 1995. These represent minimum outlays. They do not include prescription drug expenditures incorporated in in-patient hospital claims or nursing home reimbursement rates.

In Medicaid, estimates show that about 37 percent of drug spending is for sole source drug ingredient costs and 26 percent for multiple source drugs. About 10 percent is spent on over-the-counter drugs and another 27 percent is accounted for by dispensing fees to pharmacists. Almost two-thirds of the spending on multiple source drugs is for brand name drugs.

In addition, recent studies have shown that pharmacy margins, while not spiraling upward as fast as ingredient costs, increased slighter faster than inflation during the 1980s. Since you will have the author of a recently completed study before you later today I will leave a further description of the situation to him.

Growth in spending for prescription drugs under Medicaid makes proposals to achieve savings attractive, appropriate and even necessary. With this in mind, let me describe the principles against which I believe prescription drug savings should be measured. We should assure that any reforms to current Federal reimbursement for prescription drugs do not harm Medicaid recipients, for instance, by causing more physicians or pharmacists to decline to treat Medicaid patients.

We recognize that there are 50 State-run programs and not just one Federal program. We must encourage States to achieve savings that build on their current best practices and encourage further innovation. We must not interfere with market forces in ways that might result either in inflated drug prices or prices so depressed that manufacturers no longer invest in new product research.

We must not mandate program expansions such as requiring States to increase payments for pharmacists. For one, this would violate the administration's agreement with the Governors; and second, it would mitigate the positive deficit reduction effect that these proposals would otherwise have. We must insist on permanent growing savings. Reforms should be designed so savings now can be built upon in the future.

I am very pleased to hear the general agreement that no Federal proposal should involve therapeutic substitution because we believe it is an unacceptable interference with the patient/physician relationship. We would question proposals that allow a pharmacist to dispense only a limited supply of prescribed medication. This may interfere with appropriate access to needed medicine. Medicaid recipients may not return to get refills of needed medication due to transportation problems or they may incorrectly interpret the limited supply as sufficient if their symptoms cease.

In summary, we need to do all of the follow: Ensure competition, encourage manufacturers to offer Medicaid their best price, safeguard State's prescription drug coverage options, and assure access to needed medicines for Medicaid recipients.

Under these principles the following combination of policies could form an appropriate prescription drug policy. First, limiting Federal reimbursement for drug ingredients to the manufacturer's best price. To ensure continued savings we would include assurances that best prices did not rise substantially and systematically over time. To ensure continued willingness to participate in discount programs we would include limits on discounts and other manufacturing safeguards.

Second, better enforcement of existing requirements for generic dispensing through increased auditing of payment limits, tightened use of brand medically necessary language, and focused review in certain target areas.

Third, encouraging States to adopt tighter payment limits for name brand drugs when generic equivalents are available.

And fourth, fostering a competitive bidding process at the State level for a limited number of high volume, multi-source drugs with wide price differentials and assurances that the drugs from winning bids are available to pharmacies throughout the State.

Additionally, HCFA could conduct research on the cost effectiveness of certain high volume, high cost drugs and test and evaluate alternative strategies such as mail order prescriptions and best practices in State drug use review. These activities would supplement our review of how interim policies work in developing permanent policies.

In closing, let me reiterate our belief that any proposal to address Medicaid prescription drug costs should assure a balance between cost savings, appropriate Federal/State roles, access to medically necessary drugs for Medicaid recipients, adequate payment for pharmacists' services, and the protection of the physician/patient relationship.

We earnestly want to work with the Congress, the industry and health care providers to ensure changes that will constrain increasing drug costs in the Medicaid program.

Thank you for the opportunity to discuss these important issues and I would be happy to answer any questions you may have.

Senator RIEGLE. Very good. Thank you for your testimony.

Now you mentioned in your testimony that States currently are utilizing various methods to attempt to contain prescription drug costs in their Medicaid programs. As an example you cited Kansas, but noted that the State has had difficulty getting manufacturers to submit bids for its formulary. You also mentioned that the cost of Medicaid prescription drug programs nationwide is expected to increase from $4.4 billion in fiscal year 1990 to $8.5 billion in fiscal year 1995. That certain seems to be a very major increase, a virtual doubling.

Those data lead me to ask you first: How effective do you think States have been or can be in containing Medicaid prescription drug costs on a State-by-State basis? And a follow on to that, and that is: Do you think that congressional action is needed to help States control costs in their Medicaid prescription drug programs?

Dr. WILENSKY. I think that the activities today are varied. There have been some areas in which States have shown a fair amount of innovation and we think, although I will qualify this in a minute, that they have had some success. There is an area, particularly the drug utilization review area, where we think it would be prudent in the next year or two to review what has happened.

It is our understanding that there are a number of different types of drug utilization review programs. Before we would go forward in this particular area we would like an opportunity to assess the various programs, to describe them, to assess them, to have a sense about how effective they are and to get that information out.

You are correct when you indicate that a couple of States which have attempted to get competitive bidding have reported difficulties. I am concerned about whether there may be any anti-competitive activities going on. To the extent that there is concern that there may be price collusion or other activities, we have remedies available and I would certainly strongly suggest that where it appears appropriate they be used.

I do think that this is an area in which, in large part thanks to the activities of Senator Pryor, the types of savings that might be had in this area have been made clear and that there is some useful Federal legislation that could be put together. I am particularly encouraged by some of the modifications that have occurred over time, although I hope that we can try to make a few more modifications to make it even better.

Senator RIEGLE. Now one other question that I want to pose to you. That is this: You mentioned in your testimony several ideas that the administration has for containing Medicaid prescription drug costs. Among these you mentioned, and I quote, "limiting Federal reimbursement for drug ingredients to the manufacturer's best price, within limits." What exactly does that mean?

Dr. WILENSKY. It is a little vague. Let me try to give you some indication of what we are thinking about. In part it is vague because we are still working within HCFA and the administration to define some of the specifics on the option as well as working with some of the Committee members and Committee staff on these issues.

We think that the notion of a best price is the generally appropriate concept. But we are concerned because we know that there are some areas that have historically had exceedingly low prices, such as the special discount relationship with the Veterans Administration that might have started after World War II or the special relationship with Planned Parenthood that has a very low price, say, for birth control pills.

What we would like to see is the concept of having a minimum type discount and maybe a maximum type discount also on a best price, so that you try not to put the industry in positions that might be regarded as too extreme. We also are concerned, as Senator Pryor and the members that were speaking here this morning indicated, about making sure that best price does not get eroded over time; and we think there are a variety of ways to do that as well.

Senator RIEGLE. Very good.

Senator Pryor?

Senator PRYOR. Dr. Wilensky, what has HCFA done to help the States get a better deal on drugs from the manufacturers? Tell me what HCFA has done.

Dr. WILENSKY. I am not sure to date that HCFA has stepped in, other than requested specifically by States for any technical assistance. We would provide, and have on occasion provided, some assistance. There has been no direct help in terms of setting prices.

Senator PRYOR. All right.

HCFA is sitting there watching drug prices for the Medicaid programs explode, profits at an all time high for the drug manufacturers, no discounts for the Medicaid programs or the Medicaid recipients. Why has HCFA done nothing in this area?

Dr. WILENSKY. Well let me indicate some of the complications. I do not know whether I can give you the rationale for why particular policies were not undertaken in the last "X" number of years. But I can indicate to you some of the areas that we have believed were difficult.

The first is precisely how the States go about covering drugs. Because drug coverage itself is a State option, how States go about covering drugs is something that each State is allowed to set up on its own. The particular kinds of arrangements that it has, the drug utilization programs, the drugs that are covered—all the way from any drug approved by FDA to a restricted class of drugs—has traditionally, because it is an optional benefit, been left to the option of the State.

It is, as I have said, an area in which if State Medicaid directors or other people have asked for technical assistance from HCFA, HCFA has been pleased to try to provide them with information or other kinds of assistance.

It is also more difficult for Medicaid to function than it is for, say, the Veterans Administration because the Veterans Administration is not an insurance program, it is a direct delivery program. It, therefore, is actually purchasing services. It is the buyer. Whereas in Medicaid, we are the financier of a program with policies set by the States and it is a totally open system. So a lot of the abilities of the Veterans Administration or of an HMO or a hospital which are closed systems are not readily available, either to the Medicaid program in general or to the Federal Government.

This is why we have not looked at analogies of what has happened with the Veterans Administration. We are not direct providers of services like the Veterans Administration is. While we can do things or can assist in things better or differently than we have, it is really not the same as any closed system, and it makes life a lot more complicated.

Senator PRYOR. Dr. Wilensky, do you think in your past negotiations or dealings or conversations or studies of the drug manufacturers you put them on the list of cooperative or uncooperative in trying to give a better price for the Medicaid recipient?

Dr. WILENSKY. I obviously did not have any personal involvement with it. I was extremely troubled by the reports that I heard that a few States which were interested in competitive bidding were unable to get any response and I told both the States and the drug manufacturers, in a meeting early on that involved some of your earlier legislation, that if I ever heard about that I would turn to the Justice Department and to other areas in the Federal Government and encourage them to look to see whether there was any reason that a State putting out a competitive bid was not getting a response.

Senator PRYOR. The reason I asked you that question is because I think in your testimony you mentioned the State of Kansas——

Dr. WILENSKY. Right.

Senator PRYOR.—trying to lower their drug prices for the Medicaid recipient. The testimony before the Senate Special Committee on Aging a year ago, we had the Director for that program from the State of Kansas before the Committee. His testimony was, as I reflect back on it, and I am stating a general feeling of what that statement was, that when the State of Kansas attempted to bring the drug manufacturers into Kansas and say, "Look, we want discounts on these Medicaid drugs," at that time the pharmaceutical industry, basically attempted or threatened, implied or explicit, to say, "Well we just won't participate in the Kansas program anymore."

Now that is what I got out of the testimony. And yet I think you are saying that the States should go out there—small States, just like large States—in an attempt to negotiate with the very powerful and the very wealthy drug manufacturers. That is why I think we are going to have to have a Federal program, Federal legislation.

Would you think that each State should negotiate or that we should have Federal legislation?

Dr. WILENSKY. Well we were envisioning that there be Federal legislation to set out the rules under which this would occur.

Let me go back and talk about the Kansas situation and I will try to respond directly to your question.

Senator PRYOR. Mr. Chairman, are we out of time on our question?

Senator RIEGLE. Please continue.

Senator PRYOR. Thank you.

Dr. WILENSKY. This is not to explain or condone what went on with Kansas but I was extremely distressed by some of the reports I had heard. I do understand that there may have been some technical legal difficulties, particularly in the Kansas arrangement. The point that you are raising is one that is a legitimate issue—that other States have tried to do some competitive bidding in the past and have had a great deal of difficulty.

What the Health Care Financing Administration and the administration in general has been envisioning is to set up a series of rules in terms of which the bidding would occur and to set up that type of frame work, but not to have centrally organized bids.

The kind of arrangement that we have been thinking about is discounted for States that have no class of drugs excluded from what they cover, some general kind of open formulary. Open formulary, if carried to extremes, represents a very vast opening. A more general common sense thought of the term "open formulary" is that States would have, within an upper and lower boundary, access to best prices. That would be in exchange for the kind of drug classes that would go on a formulary.

We have also been considering the notion of requiring States to do competitive bids for a limited number of their high volume, high cost drugs. Within that context, I think both because of the activities of yourself and your colleagues, whatever has been the past inclination of the pharmaceutical industry, you have clearly gotten their attention.

Legislative safeguards ought to make sure that best prices do not get whittled away over the future and that other unwanted changes are made, but I would not say that just because this is the difficulty you have had in the past, that this will necessarily be the difficulty that you will have in the future. I think you really have gotten their attention.

Senator PRYOR. Well, Dr. Wilensky, I owe that to Chairman Riegle and Chairman Bentsen, because I have not been able to get the attention of the pharmaceutical manufacturers. In fact, on two occasions as Chairman of the Special Senate Committee on Aging I have invited them to come and state their positions. They have refused to do so up until today. This is a first. I am indebted to Chairman Riegle for really getting their attention. I just happen to be a lowly member of this committee. I appreciate his opportune scheduling of this meeting so I could be here and have a chance to participate.

Now you said that you are thinking in HCFA of a set of rules whereby there might be some savings. Now how long does it take from the time HCFA starts thinking about a set of rules and the time that you actually have those set of rules? How long does that take, Dr. Wilensky?

Dr. WILENSKY. Well as I think you know, since we have been talking with your staff, Senator Pryor, HCFA has been working on this area for the past 6 weeks or so. What I was indicating by that somewhat elliptical statement is that we do not yet have a formal legislative proposal but we do have the general outlines and concepts of what we think such a proposal would be like. We have been working with our colleagues at OMB. Although for the most part they have not been available.

Senator PRYOR. They are out at Andrews Air Force Base now.

Dr. WILENSKY. Yes.

Senator PRYOR. You have been working with us on all of this and we appreciate very much your input. And you say you are going to adopt a set of rules. I have introduced two bills.

Dr. WILENSKY. Yes, that is correct.

Senator PRYOR. What is wrong with those bills?

Dr. WILENSKY. Let me indicate areas. I think, as has been mentioned today, that "Pryor 2"—S. 3029—has addressed some of the concerns that existed with respect to the first piece of legislation.

Senator PRYOR. I also say that I think we are technically out of time, Dr. Wilensky. But go ahead and just tell me briefly what you think is wrong with S. 2605 and then the bill I introduced last Wednesday.

Dr. WILENSKY. Okay.

Senator PRYOR. That will suffice.

Dr. WILENSKY. First, of course, is that S. 3029 has been recently introduced and we would obviously like the chance to go through this bill more thoroughly.

Senator PRYOR. It has indexing in it.

Dr. WILENSKY. Yes.

Senator PRYOR. Do you support indexing?

Dr. WILENSKY. We can support a type of indexing. We are a little concerned about the particular form of indexing. I would like to make the distinction. Both your Senate bill and what I would regard as a relative to it, which was embodied in some proposals that the Merck Company has put out as a second round, index a discount relative to CPI.

My concern about the explicit way of ensuring that you keep the best price over time is that it sounds an awful lot like a price control to me. It sounds like a price control to me because it pegs a price at a given point in time. It increases it at a fixed amount over time. That sounds a lot like price control.

Let me give you an example of what I think would meet the legitimate concern you have raised, which is, how do we know that best price will not be resolved by simply upping what the best price has been to the average price or more and, therefore, lose best price over time. I gather that is the concern that you have raised.

It would be possible to take an index of the manufacturer's sole-source drug prices weighted according to the sales in which they occurred, and to index the price over time; if the index of a manufacturer's sole source line goes above CPI or MCPI increases you could enforce an additional rebate.

Why do I regard this as a little less objectionable? It is because you are not tying the specific price that you are willing to reimburse absolutely to where you were in a base line with no deviation. It does not matter so much if a single drug gets out of line as long as the weighted index of what that manufacturer charges on a sole source stays within approximately the CPI. A little bit of movement reflecting market pressures or whatever, would, to my mind, be much more acceptable.

So I appreciate the concern you were raising. I think there is a way to ensure for scoring purposes—Senator Hatch may feel comfortable that it is an easy problem to fix; I am a little more concerned as to how easy it would be to fix—and in fact to assure ourselves, that savings really would occur over time. But this need not be quite as rigid as tying it to a base year indexed by some measure. I really do think that gets us into a rigidity we do not need.

Senator PRYOR. Well I have no pride of authorship in all this. I would be satisfied frankly if we could get an indexing system based on what our own American drug manufacturers sell to the Europeans on and start it at that. Make the manufacturers give us in this country the same prices for which they sell these drugs in Europe. But I know that is not going to work.

Mr. Chairman, I want to thank you for allowing me to extend the time, and also Dr. Wilensky.

Senator RIEGLE. Thank you.

Let me say we are please to have Dr. Wilensky here. This will be the first of subsequent conversations, I think it is fair to say. Let me thank you. We will have some questions for the record I think from other witnesses and will excuse you at this time.

Dr. WILENSKY. Fine. Great. Thank you very much for allowing me to testify here, Mr. Riegle.

Senator RIEGLE. Very good.

[The prepared statement of Dr. Wilensky and responses to questions appears in the appendix.]

Senator RIEGLE. Let me now call our first panel which consists of two experts on the pharmaceutical industry and prescription drug costs and cost containment. They are here to give us some background information on these topics and the concepts involved in the proposals being proposed and discussed today.

Let me invite now Stephen Schondelmeyer, who is a pharmacist and a Ph.D., and is the Director of the Pharmaceutical Economics Research Center, Purdue University; and as well, Judith Wagner, Ph.D., who is a Senior Associate at the Office of Technology Assessment.

Both of them will provide background information on drug pricing, drug price increases and cost containment methods. Just looking ahead, we have got an important number of witnesses down the line here, and it is very important that we get through all of them today. This panel will be followed by a panel consisting of people representing major pharmaceutical firms in the country, to be followed by a panel of very important public interest group persons and representatives speaking on this issue, and then a final panel with people ranging from State Department of Health officials to members of the Legislative Black Caucus in Louisiana and two others that I will not mention now, but to give us a range of other opinions and perspectives.

So with that, let me say to the two of you, we appreciate your being here and your patience. I want to stick to the 5 minute presentation summary. We will make your statements a part of the record.

Mr. Schondelmeyer, why don't we start with you?

STATEMENT OF STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D., DIRECTOR, PHARMACEUTICAL ECONOMICS RESEARCH CENTER, PURDUE UNIVERSITY, WEST LAFAYETTE, IN

Mr. SCHONDELMEYER. Thank you, Mr. Chairman. I appreciate the opportunity to provide input into your Committee. I am Stephen W. Schondelmeyer, an Associate Professor of Pharmacy Administration at Purdue University in West Lafayette, Indiana. I also serve as the Director of the Pharmaceutical Economics Research Center at Purdue.

It was my pleasure last year to have served on the short-lived Prescription Drug Payment Review Commission that was established under the now repealed Medicare Catastrophic Coverage Act of 1988 and we in our brief time began to look at and address some of these issues in that context.

The goal of my remarks today is to address three major questions. Why are we dealing with legislation on Medicaid drug prices and expenditures? What are the options for addressing the problem? What constitutes sound public policy?

Let's begin by asking why are we dealing with this legislation on Medicaid drug prices and expenditures. Federal and State entitlement programs over the past few years have been growing at a faster rate than the revenue sources which support them. Although a number of factors have contributed to this growth, and the drug expenditure growth in particular, the drug product cost grew five to seven times faster than any other single component that contributed to the Medicaid drug budget. So drug product costs were the fastest growing component of the expenditures in the drug program under Medicaid.

Many of the attempts at expenditure control by Medicaid programs at the State level have focused on limiting pharmacists fees and drug product cost reimbursement to pharmacists. That reimbursement limit to the pharmacist though is not passed on, or the pharmacist is not able to pass it, on to the manufacturer in most cases.

While these approaches have worked for controlling pharmacists' fees, it is now clear that the growth in manufacturers' drug product costs cannot be controlled by limiting the pharmacist's reimbursement and we need new mechanisms and alternatives.

This brings us to the second major question: What are the options available to manage drug expenditure growth in State Medicaid programs. Some manufacturers have begun to offer discount or rebate programs, but only after the threat of Federal legislation came with the introduction of S. 2605 by Senator David Pryor in the spring of 1990.

These manufacturer offered discount programs are voluntary on the manufacturer's part and place in most cases significant restrictions on the cost management options available to State Medicaid programs, such as their use of formulary systems and prior authorization programs.

Drug manufacturer agreements at the State level, I feel, are poor public policy for several reasons. First, every manufacturer has its own plan and form of agreement, including special reporting and accounting methodologies. A State could end up with 15 to 30 or more different plans and increase significantly their administrative costs in administering those plans.

Second, the plans are voluntary for the manufacturers and will result in Medicaid programs becoming economically dependent on the manufacturer's continued voluntary cooperation. This situation could be leveraged by manufacturers to persuade State Medicaid programs not to propose or seek further cost management tools over the prescription drug program.

Third, it is very conceivable that manufacturers would offer voluntary discounts only to the largest States, leaving the smaller but no less important markets without access to discounts. The larger States might do all right on their own but we need to assure equity for all States.

In other words, I think Federal legislation with a standardized discount program and reporting system for all States would resolve each of these concerns and provide equity among the State Medicaid programs in our country and equal access to medicines for all indigent patients in this country.

What constitutes sound public policy? First, the legislative approach chosen should have a high potential for real economic impact on Medicaid drug expenditures. For example, discounts alone are only relational in nature and may not have any real impact on expenditure levels unless both price level and rate of growth are addressed in conjunction with defining such discounts.

We probably all have fallen prey to the discount shopper mentality which convinced us to buy something at 30 percent off only to find the same item next week at another store for less than the original sale price. What I am saying is, the real issue is the net price paid. It does not matter what the size or the amount of the discount is.

I do feel that the new Pryor legislation, S. 3029, constitutes a very well fleshed out approach to providing a meaningful drug expenditure tool for State Medicaid programs. I think our nation's Medicaid programs would be remiss in exercising their authority and their market power as one of the largest buyers in this marketplace if they did not use that market power to achieve the best price. We would think that any private business that did not use such market power to achieve and negotiate best prices would be failing in their responsibility to their stockholders. I think any State Medicaid program that fails in such would be failing in their responsibility to the citizens of this country.

Thank you.

Senator RIEGLE. Very good. Thank you very much. We appreciate that and will make your full statement a part of the record. I appreciate your working within this time constraint. That is helpful to us.

[The prepared statement of Mr. Schondelmeyer appears in the appendix.]

Senator RIEGLE. Dr. Wagner, we would like to hear from you now.

STATEMENT OF JUDITH WAGNER, PH.D., SENIOR ASSOCIATE, OFFICE OF TECHNOLOGY ASSESSMENT, WASHINGTON, DC

Dr. Wagner. Thank you, Mr. Chairman. At your request my colleagues and I at OTA reviewed the evidence on prescription drug cost containment, emphasizing its impact on pharmaceutical R&D. As you know, we are currently undertaking a study of the costs of and returns to pharmaceutical R&D. My remarks today are based partly on what we learned so far from that assessment, but most of what I have to say today is independent of that study.

In keeping with OTA's general policy my comments today will address general cost containment alternatives, not specific legislative proposals. If we accept the fact that effective cost control of Medicaid prescription drug expenditures is urgently needed, the next question is: What general approaches will provide the greatest control of overall Medicaid costs with the least possible disruption of Medicaid patients' access to needed medicines and the least harmful affects on the flow of new pharmaceuticals in the future?

We looked at cost containment over the life cycle of pharmaceutical products, from the market entry of a new compound as a single source drug with patent protection to its transition to a multiple source drug when patent protection expires some 7 to 15 years later.

If you take revenue away from multiple source drugs by imposing price controls and/or by encouraging generic substitution you will do little to hurt R&D. This is because today's investments in R&D are governed mainly by the future stream of returns expected from the drugs that may come out of the R&D process. These expected returns extend many years out into the future and must be discounted back to their present value to the firm at a rate equal to the firm's cost of capital.

Because generic competition comes at the end of a drug's product life cycle, lower expected returns many years in the future when patents expire are much less important to the R&D decision today than are changes in potential market returns when a drug is first introduced.

All other things equal then, for the sake of innovation, control over expenditures for multiple source drugs is very much preferable to control over expenditures for single source drugs; and cost control methods that tend to focus on the newest single source drugs by delaying marketing or adding uncertainty to reimbursement decisions or restricting the launch prices of new drugs are likely to be most damaging to innovation.

But what is the potential for cost control of multiple source versus single source drugs under Medicaid? Two States—New York and Florida—provided us data on their programs. In New York at least 41 percent of all claims are for multi-source drugs. And in Florida almost 40 percent of prescriptions are available from multiple sources. In both States studies conducted in 1989 showed that a substantial proportion of the prescriptions or claims were filled with name brand drugs at prices substantially higher than the generic price.

Florida determined that 22 percent of all prescriptions, that is including name brand and generics, multiple source and single source, in the State were written with the physicians brand medically necessary override. In New York, name brand drugs held 63 percent of the multiple source market volume.

Judging by these two large States the potential for savings from increases in the rate of generic prescribing is high. Florida officials told us they now refuse to pay more than the generic price for a multiple source drug that has a physician brand override. The physician can order; the pharmacist can dispense; the State simply will not pay more than the generic price, except for 11 drugs that are on their negative formulary.

Now turning to single source drugs that make up about 60 percent of the total volume of prescriptions in New York and Florida and a higher proportion of total revenues, it is much trickier to control the revenues from these drugs without restricting access or without discouraging R&D. In general, restrictive formularies, though the jury is still out on whether they reduce costs, do focus on new drugs by delaying or denying product introductions in certain States.

If it is necessary to focus cost control on single-source drugs then policies that permit freedom of access to new products and that leave the companies free to set their own launch price for new drugs are likely to have the least negative effects on both access and innovation. Up to now Medicaid formularies have probably had little influence on R&D or innovation, though they may have limited access in some States to new drugs. Medicaid as a whole is only about 13 percent of the U.S. market and the U.S. pharmaceutical market is only about 25 to 30 percent of the world market.

Given the down side to policies that affect the incentives to innovate and patients' access it makes sense to think twice before we go on a national policy that could have an impact on R&D in the future.

Thank you.

Senator RIEGLE. Thank you very much, Dr. Wagner.

[The prepared statement of Dr. Wagner appears in the appendix.]

Senator RIEGLE. Senator Pryor?

Senator PRYOR. Mr. Chairman, I have several questions that I would like to submit in writing to both of these very distinguished witnesses, but in view of the time situation, and that you are going to have to leave shortly, I would just ask one at this time to Dr. Schondelmeyer. Once again, I will be submitting written questions.

The manufacturers today, I think, Dr. Schondelmeyer, will be advocating voluntary programs whereby each State would basically negotiate with each of the manufacturers on particular drugs.

What about a voluntary approach that they probably are going to propose? What does that do to the patient, to the taxpayers, to the Medicaid recipient, and also to the doctors?

Mr. SCHONDELMEYER. Well as I stated in my presentation I do not think that a voluntary approach on a State-by-State basis, manufacturer-by-manufacturer would be very efficient use of Medicaid resources. Most State Medicaid programs, and I have worked with a number of the pharmacy programs administrators in the State Medicaid programs, have enough to do already without having the drug company representatives beat down their doors to get their drug on a formulary or to get a rebate program signed.

Most of these programs are not even staffed for this type of activity and this would increase their administrative workload significantly to have to manage such activities; and most of these plans have separate reports that the manufacturer wants on the sales volume of their drugs and they want it in just a certain way so that they can put it into their computer system and track it. So they are asking the Medicaid program to do some work and give them some market data back to help them analyze and sell their products better in that State, and putting a lot of administrative expense off on the States.

I feel that also the individual States, and particularly the smaller States, are at a significant disadvantage on the one-on- one negotiations. There is much less leverage or reason for manufacturers to go into the smaller States and offer these programs.

Senator PRYOR. Thank you. I will have further statements that I will submit and ask you to answer for the record.

Thank you, Mr. Chairman.

Senator RIEGLE. Very good, Senator Pryor.

Let me just ask one question and then I am going to give you some questions for the record and call up the industry panel that is here.

I assume that both of you are somewhat familiar with the best price proposals that have been put forward by some pharmaceutical manufacturers and by Senator Pryor in his recent bill. I am wondering, can you tell us what, if any, long-term effects these proposals might have on the pharmaceutical market and particularly prices to other purchasers?

Dr. WAGNER. I believe in some respects the best price proposals put forth by some of the manufacturers may in fact improve the signals for R&D, that is by piggy-backing Medicaid expenditures onto the price sensitive segment of the market for single source drugs. That is, by linking Medicaid prices to prices that are given to HMOs when a drug is a close therapeutic substitute, because the HMO has a lot of market power itself, will send signals back to drug companies that the "me too" me toos, the real copies, are not going to be as profitable in the future. But the significant new drugs will not be affected in terms of their ultimate market returns.

Senator RIEGLE. Did you want to add to that?

Mr. SCHONDELMEYER. Sure, I would be glad to comment. I think in our marketplace for pharmaceuticals we have had for a number of years some very unique discounting arrangements that have not necessarily been based on market power or position or quantifiable discounts or well-defined discounts. There are some very disparate discounts in this marketplace, and we have had examples on some charts in this hearing and other hearings before Congress.

I think to say that discounts to Medicaid would not change this market would be an oversight. Certainly it will change some of those pricing practices to certain buyers in the marketplace. But in just the same way as if we had a situation where there was discrimination with respect to race or other criteria in our society, we do not want to freeze that discrimination in place just because changing it would be inconvenient to someone.

I think this Medicaid discount program will put us through a period of great flux and instability for many buyers of pharmaceutical products. But I think having the Medicaid programs exercise their market power and begin to say, "we deserve the same level of discount if we meet the same criteria as another Government Agency or the same criteria as another organization that buys on volume" would be appropriated. Medicaid programs would be remiss if they did not exercise that power and begin to ask for those prices.

There will be some sifting out. I do have one concern about S. 3029 that I would like to raise at this time in just a brief way that relates to that. That is, I do not feel that it is in the best interest to index the best price over time, but rather to index the average manufacturer's price at a certain point in time and then require that the price that be given to the Medicaid program be the lower of the best price or that indexed manufacturer's price minus 10 percent or the current manufacturer's price minus 10 percent. This approach uses a lower of criteria as we have used with pharmacist's fees and other programs in the Government.

I do not think this type of expenditure control attempt is inconsistent with other actions that Congress has taken in their efforts to control physician's expenditures under Medicare or hospital expenditures under Medicare. I think this is quite consistent with other public policy with respect to health care costs and expenditure control.

Senator RIEGLE. Our next panel consists of representatives of the pharmaceutical industry, including officials from several companies that have developed legislative proposals for giving discounts to the Medicaid program. Unfortunately, we do not have the time to hear the details of each company's proposal, but their representatives will answer questions about their individual plans.

As you are taking your seats let me just introduce this panel of witnesses. We have Mr. Gerald Mossinghoff, who is President of the Pharmaceutical Manufacturers Association, who will present on behalf of the industry, the industry view of the Pryor bills and industry principles regarding cost containment measures. He will be accompanied by a number of company representatives who have ideas that they have advanced in one form or another. They include Mr. John Zabriskie, who is the President of Merck Sharp & Dohme, based in Raway, New Jersey; Mr. Kenneth Bowler, who is Vice President for Federal Government Relations for Pfizer, Inc., based in New York City; Mr. Robert Ingram, who is the Executive Vice President of Glaxo Inc., based in Triangle Park in North Carolina; and then from my home State, Dr. Theodore Cooper, who is the Chairman of the Board and Chief Executive Officer of the Upjohn Company, based in Kalamazoo, Michigan.

I am going to very shortly call on you, Mr. Mossinghoff, to give the statement on behalf of the industry association. When you have finished making that summary comment I am going to pose one question to Dr. Cooper that I particularly want him to address. And then before long I am going to have to leave for another requirement that I must meet and Senator Pryor will take over and chair the session for the remainder of the morning and early part of the afternoon here.

With that understanding I am going to make your full statement a part of the record and I would like to hear your summary comments now. Then I am going to go to my question for Dr. Cooper and then we will open it up for questions of the various ideas that I know different companies have here. So we would be pleased to hear from you now.

STATEMENT OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, DC, ACCOMPANIED BY JOHN L. ZABRISKIE, PRESIDENT, MERCK SHARP & DOHME, M. KENNETH BOWLER, VICE PRESIDENT, FEDERAL GOVERNMENT RELATIONS, PFIZER INC., ROBERT A. INGRAM, EXECUTIVE VICE PRESIDENT, GLAXO, INC., AND DR. THEODORE COOPER, CHAIRMAN OF THE BOARD AND CHIEF EXECUTIVE OFFICER, THE UPJOHN CO.

Mr. Mossinghoff. Thank you, Mr. Chairman. Mr. Chairman, I would like to make one major point regarding the industry as a whole and then give the industry's views as they have been developed in just the last few days on Senator Pryor's second bill, Pryor 2, and then summarize each of the companies as the staff of the Committee asked me to do—each of the company's proposals in their terms.

The first point is, although the overall cost of medical care in the United States has represented an ever-increasing share of gross national product, prescription drugs have claimed less than 1 percent of GNP for the past 25 years. The percentage was 0.84 percent in 1965 and 0.86 percent in 1988, the last year for which HCFA data are available. While claiming a small and remarkably constant percentage of U.S. GNP, America's U.S. research-based pharmaceutical industry has established itself as a world leader in high technology, one that has consistently enjoyed a positive balance of trade.

Turning now to the bill, S. 3029, I would like to make several points on that bill based on our initial reading of it. First, statements made regarding the bill could lead to an interpretation that a drug would be automatically available under the bill to patients in the Medicaid program if the manufacturer provided a rebate or discount. A reading of the bill, however, indicates that this is not the case. Even if the manufacturer provided a rebate, States could still subject any drug to a prior-approval system.

In an attempt to simplify the current unsatisfactory prior approval systems, quite noteworthy, the bills would provide for an immediate telephonic response to a request by a doctor for prior approval. The bills do not, however, provide any criteria for prior approval or disapproval or provide any appeal procedure if the doctor is overruled by the bureaucrat on the other end of the line.

By permitting prior approval for some drugs and not other drugs, a State could very well establish a de facto restrictive formulary under this bill, even though all manufacturers would be required to provide a rebate. All of this is in sharp contrast to what is happening in the States now in negotiations for discounts and rebates in the Medicaid program. States are providing automatic access to new innovative drugs in return for discounts and rebates.

Mr. Chairman, I was delighted to hear some of the comments this morning—particularly by the two distinguished members of the House of Representatives. PMA would be glad to work with you, with Senator Pryor and with the Subcommittee to make sure the bill does provide automatic access to drugs. It is an easy change to be made in the bills to provide automatic access without this cumbersome prior-approval system that Senator Bradley mentioned, and we would be pleased to work with you in that regard.

Second, S. 3029 is inherently unfair, I would submit again with all respect. Its economic impact would vary widely from company to company. The bill, for example, would index a best price given to the Department of Veterans Affairs in order to calculate a rebate in the Medicaid program. Many of our companies are reported as having given deep discounts to the DVA, a practice that for some goes back to World War II. Those companies would be hit hardest under the bill.

Penalizing a company for having a practice of giving a deep discount to the Veterans Administration—a practice which I would submit is not reprehensible—is not sound public policy.

Third, the idea of price controls is inimical to this country's free market economy. Price controls are totally unreasonable in the absence of controls over a manufacturer's cost of doing business, including wages, energy, transportation, et cetera. A quintessential feature of world-wide developments is that free-market forces serve society far better than centrally planned and administered controls.

There was a provision—I was going to comment on it—that appears almost punitive in its nature—and I did receive and am very grateful for a letter from Senator Pryor dated yesterday—we have Senator Pryor at least working on Sunday, I know that, on this measure. I do appreciate your letter, Senator, and I will not make that statement in my prepared remarks.

But I would say that the thrust of the bill in the multi-source arena is discriminatory. Companies doing exactly the same thing—that is, making and selling a multi-source drug—are treated very differently depending on whether they are an originator or a copier, with the originator being disadvantaged. The originator must give a best price discount; the copier merely only gives a 10 percent discount, and yet each company is doing exactly the same thing—manufacturing and selling a multi- source drug.

Finally, there is no justification for the provisions to take money in the form of rebates from manufacturers in order to pay a portion to major chain stores, supermarkets and large mail order houses among others. That may be good politics, but it is not sound policy and does nothing for the Medicaid program.

Mr. Chairman, even though the orange light is on, maybe I should very quickly summarize the company proposals.

Senator RIEGLE. Please do.

Mr. MOSSINGHOFF. First, the Merck proposal. Under the Merck plan, called the Equal Access to Medicines and Best Price Discounts Act, manufacturers would be required to grant best price-based rebates on all of their single-source form prescription drugs to every State's Medicaid program as a condition for reimbursement.

Such rebates would equal the difference between the manufacturer's price to wholesalers and its "best price" offered to any U.S. purchaser. The minimum discount under the Merck plan would be 10 percent. The Merck plan would assure Medicaid patients access to a full range of pharmaceutical therapies by prohibiting States from using formularies, prior-authorization requirements or any other restrictions in the single-source prescription drugs of those manufacturers that provide rebates.

The Merck proposal further calls for a ceiling on discounts that would be phased out over a 5-year period. Specifically, the ceiling would be 15 percent in the first 2 years, 20 percent in the third and fourth years, and 25 percent in the fifth year. There would be no ceiling in the sixth and subsequent years.

Merck voluntarily announced the plan to the States in April. Since then 32 States have adopted it, and 10 more have declared their intention to embrace it. These 42 States account for over 90 percent of all Medicaid drug expenditures in the nation.

The Glaxo proposal is designed to provide Medicaid with the same level of discounts achieved in the managed-care market. Glaxo has offered Medicaid agencies the best discount it gives to those managed health care organizations that, like Medicaid, reimburse for prescription drugs dispensed by pharmacies to participants. Under the Glaxo proposal, each State Medicaid agency would receive a discount from the manufacturer based on the number of units of a specific drug dispensed by pharmacies to Medicaid beneficiaries.

In return, the States would be prohibited from restricting access of Medicaid beneficiaries to the manufacturer's products.

The Pfizer proposal has five key elements. First, the manufacturer would be required to make quarterly Medicaid discount payments to Medicaid programs in amounts that assure that the programs receive the best market price available in the United States. Effective this October, States that reimburse prescription drugs would be required to reimburse all single-source drugs with no requirement for prior authorization. The Federal Government would not be permitted to establish a Medicaid formulary. All sectors of the marketplace for prescription drugs should contribute to Medicaid savings.

The possible options for multi-source drugs include codifying the current HCFA regulations, use of the same best price formula as proposed for sole-source drugs, or competitive bidding.

Finally, in any State that provides open access manufacturers would make payments equal to one-third of the Medicaid discount payment for the periods from enactment to next October, and two-thirds of the Medicaid discount payment for the period October 1, 1991 to October 1, 1992.

The Upjohn proposal is for a formula offering 75 cents claims processing and 3 percent of the total prescription cost to provide a weighted prescription rebate. Total prescription price provides a simple and convenient anchor on which to calculate future rebates and includes increases in pharmacist reimbursement.

Advantages of the weighted prescription formula, according to Upjohn, are (1) on average the rebate prescription would range from less than $1 to $2.48 per supplier, with the major research pharmaceutical manufacturers contributing the larger rebates; (2) administrative simplicity; (3) rebate calculations are possible from existing data, specifically the MMIS data; and (4) total rebate savings would exceed $300 million, assuming 220-250 million Medicaid prescriptions and an average of $1.30-1.40 per prescription.

Several other PMA companies have endorsed one or more of these proposals. Perhaps more important, more than a dozen PMA companies are now reported to be negotiating discounts and rebates with Medicaid officials; these companies represent slightly more than one-half of the Medicaid single-source drug market. As I have already indicated, 42 States are involved in these negotiations.

Thank you very much, Mr. Chairman, for this opportunity.

[The prepared statement of Mr. Mossinghoff appears in the appendix.]

Senator RIEGLE. Very good. Let me now pose a question to Dr. Cooper, as I indicated earlier that I would.

Dr. Cooper, again, we are pleased to have you here. We are very proud that the Upjohn Company is based in Michigan. You have had a distinguished record over many years. That is widely known of course. You have come forward with a proposal of your own now as a company. I think that type of response and contribution of thinking and initiative by the companies is an important part of what is now this debate on Medicaid drug reimbursement proposals. So we are pleased to see that initiative.

Now I understand that Upjohn has a proposal which is different from the best price approach that has been presented to the Committee. I am wondering if you could please explain the Upjohn proposal and its advantages. And at the same time, would you give us your perspective on a best price approach as a mechanism for cost containment.

Dr. COOPER. Thank you, Senator. I will be glad to answer those questions. The Upjohn proposal was conceived as trying to reach the objectives of returning money to the Medicaid program in a way that would be as administratively simple as possible because none of the discussion this morning thus far has commented on the complexities of managing and administering any of the other proposals, either in legislation, OMB or from the other companies.

These estimates of the cost of administering the program have been substantial in themselves. In a previous incarnation I had the privilege of trying to implement what was known as the MAC program in the mid-70s. The administrative difficulties greatly outstripped any of our estimates at that time. So administrative simplicity was one of the great objectives that we had to do.

The second is, we wanted a mechanism that would not disrupt current business practices, at least in my view what I would construe as best price changes various times during the year in various mechanisms to various customers. In answer to the question that you asked Mr. Schondelmeyer, it certainly would have a best price program in the manner that has been discussed by any of the proposals, would have an impact on how we would do business with a variety of customers.

There are data available. It could be paid every quarter on a reliable basis and could be weighted in such a way that if the 3 percent is not adequate, if that is the non-starter, that is a matter of negotiation. The exact amounts, including an equivalent up to the Merck 10 percent could easily be achieved. What it amounts to is paying an administrative fee of 75 cents for each prescription. That is the data that we have received that seems to be the cost to Medicaid of administering that part of their program, giving that as one part of the program, and the other is a weighted program on the amount of sales that any company makes over the time period, by quarter or by year.

In that way every supplier participates. The low cost prescription participates less, the higher cost more. If prices increase the tax increases essentially, but that could additionally be governed by a escalator Governor. So there are important differences in the way we would approach the negotiations with the States or with the Federal Government as a whole, as opposed to trying to set up an elaborate mechanism to rationalize what constitutes best price in any economic cycle.

Senator RIEGLE. Let me ask you this, Dr. Cooper, over the years we have had insurance—the insurance companies in the United States—regulated at the State level. It is one of the anomalies in our financial regulation system. They are not subject to a broad national regulation, so they deal with each of the 50 States and you have a pattern of that difference that has arisen over the years.

Interestingly just this last week the insurance industry—I was not present at those hearings—appeared before the Senate Commerce Committee and suggested that perhaps the time had come to go to some manner of at least partial Federal standards and regulation and oversight so there could be a uniformity, and we would not have a situation where 50 different fields were operating at once. They testified that the time may have come, for a variety of reasons, at least in the minds of some, that it is time to have some kind of a Federal structure in place that would work to everybody's benefit.

I am wondering, what you think about this question of individual States working something out, versus having a Federal approach that in a sense is a 50 State answer. I would like you to just reflect aloud on that for a minute.

Dr. COOPER. I would think that the ability with our program to respond to a Federally-mandated, country-wide program would be quite easy. I do think that we have been negotiating with a couple of dozen States already. We have come to terms on four, several are pending. So we could do it on an either or basis because the kind of negotiation is rather simple. One does not have to get into trying to validate pricing and the likes.

Senator RIEGLE. But is there any inherent argument that says that this should be done State-by-State, and all these different venues and so forth? If we have something that needs to be dealt with in an appropriate fashion, why not do it in terms of a national answer and in a sense——

Dr. COOPER. Well in this situation I would favor a national answer. There is a philosophical difference on all kinds of activities between States prerogative and Federal.

Senator RIEGLE. I understand. Right.

Dr. COOPER. And just as in the insurance industry, if you can pick and choose what activities you would like to facilitate, equity across the country, a Federal answer is appropriate. In this case I think it is.

Senator RIEGLE. Very good.

Senator Pryor, may I invite you to come over and take the chair at this point. I must leave at this time and you gracious agreed to chair the rest of this hearing today. Let me invite you to take the chair at this time.

Let me also say that you are next up for the questions. So it is appropriate that you get the chair.

Senator PRYOR. Thank you, Mr. Chairman.

Mr. Mossinghoff, did you complete your statement? Dr. Cooper, did you finish answering your question by Senator Riegle?

Dr. COOPER. I believe I answered Mr. Riegle's questions. I have a statement, which as with the others, we would submit for the record.

Senator PRYOR. Thank you. All of the statements of the witnesses with this panel, as with other panels, will be placed as an appropriate part in the record.

Senator PRYOR. You know, this hearing really is about a very, very simple issue. If I could, I would like to have a chart placed here, and here is what the issue is about. It is about drug price comparisons.

We see, for example, Pfizer's price for its antiarthritic drug Feldene. Medicaid pays $1.68, VA and HMOs pay 87 cents, a difference of 93 percent. For Glaxo's product Zantac, Medicaid pays $1.18 per capsule, the Federal Government 79 cents per capsule. For Seldene, Medicaid pays 61 cents, the Federal Government 40 cents.

That is what this hearing is about; to see if there is not some way to recognize that Medicaid is a very, very large user of prescription drugs. Also, that these prescription drugs go to the poorest of the poor, our Medicaid programs are financially strapped. Our Federal involvement with the Medicaid programs is at issue probably as we speak at Andrews Air Force Base. All we are attempting to do is to see if there is not some rational way that we can basically sort of level the playing field with those prices.

As I have stated earlier, I have introduced two bills. Both have been discussed at some length here today. I am not certain that either of those approaches is going to be what we finally act on. I have no pride of authorship. I am looking for suggestions. I think that we have gotten a few suggestions this morning. We are reasonable to any offer, but something has got to be done.

Mr. Mossinghoff, you talk about the free market economy. Well, what the free market economy has brought to us is that chart, the highest priced drugs anywhere today are paid for by those least able to afford them. That is what the free market economy you speak of has brought us. We cannot stand it. It does not make sense. It is unjustified.

It has brought us also a 152 percent increase in ten years in the cost of prescription drugs, versus the 58 percent increase in the general price inflation. So we have to do something. That is what we are attempting to do with these two pieces of legislation.

Let me ask a question, Mr. Mossinghoff. What has the Pharmaceutical Manufacturer's Association done to cooperate with the Medicaid programs in the States to achieve the lowest possible price?

Mr. MOSSINGHOFF. Mr. Chairman, as I have testified at some great length before your Committee on Aging, PMA as an association does not get involved in whether companies bid or not bid. Indeed, we cannot get involved in that. We do not get involved in pricing policy. We are an association of very tough competitors. Under antitrust guidelines which our counsel enforces on us continually, we do not get involved in that.

Senator. PRYOR. By that, do you mean, not the association, but major PMA companies?

Mr. MOSSINGHOFF. I have outlined in my statement that States in which more than 90 percent of the Medicaid beneficiaries live, are now in play with more than a dozen PMA companies. They have decided on their own. And as I said in the public hearing—I do not know if it was in this room, but in a room much like this up here when we were in a state of concern about the OMB therapeutic substitution proposal—you deserve credit, I think, for that movement.

The key element to the movement is access for discounts or rebates. So all of the patient groups that we worked with on opposing particularly the OMB proposal, but also S. 2605, that is the overarching goal of those groups. That is, that Medicaid folks have access to the best medication available if the doctor wants them to have it.

As I say, the key element of the State negotiations that PMA companies are involved in now is that it is a quid pro quo. In return for a discount or rebate—not a Veterans Affairs discount, I do not imagine, but a fair discount—they are having automatic access to new medications. We would like to work with you and the Chairman of this Committee to see if we cannot reshape the bill somewhat to provide that.

That is a reasonable goal and it is one that hundreds of patient groups and legislators agree with.

Senator PRYOR. Mr. Mossinghoff, if the Veterans Administration can purchase these drugs for these prices, why cannot the Medicaid programs purchase at the same price?

Mr. MOSSINGHOFF. Let me explain—and I do not mean to be technical—that Medicaid does not purchase anything. Medicaid is not the largest purchaser of drugs. Medicaid is a reimburser for hundreds of millions of small purchases, at average, $15 per prescription. I think in a socioeconomic concept, Medicaid looks more like, for the prescription drug area, the food stamp program than it does the VA program. They do not purchase it; they do not take it to a loading dock. They use the existing means of distribution, as the food stamp program does, and they simply provide a way for the deserving people, people that need the medication, to get the medication.

Many of the VA discounts I am told go back to World War II when Johnny came marching home. One of our companies told me—one of the best CEOs in the business, I would submit; and I am not going to name him at this hearing because that is not a good thing for a President of a trade association to do—that he did not know what they were doing in the VA program so he went back and asked what they were doing. The answer was that they were giving very, very deep discounts.

The question is: Why are you doing that? One, it started in 1943; and two, it is such a small percent of their business that it did not show up on the balance sheet.

Senator Pryor. The Merck proposal and the Pfizer proposal both indicate that they are willing to sell at the lowest price. Does this indicate a trend that the industry is now willing to sell to Medicaid at the VA price, which is the lowest price?

Mr. Mossinghoff. Well certainly I must make very clear that the Board of PMA has not taken a position on any of the proposals. Two of them do talk about the best price, but they also include a phase-in period. And one specifically includes a cap on the discount. It is, I believe, 15 percent for 1990–91; 20 percent for 1992–93—so that there can be some—the adjustments that Mr. Schondelmeyer was talking about, there can be some adjustments in price and practices so they both include that.

They also do not include making the price that is locked in history forever. If you as the CEO of a company had a very, very low price that was established based on policies in World War II and it was perfectly legal—and as I point out in my statement, not only legal, but certainly not reprehensible to give VA a discount from World War II on—and you suddenly found public policy saying, that is right and you are stuck with it forever, I would submit you would find an inherent unfairness in that.

Senator Pryor. Mr. Mossinghoff, you mentioned OMB a few moments ago. Do you feel that OMB or CBO would actually cost out the savings merely based on the promises of the drug industry?

Mr. Mossinghoff. I believe they should. I will not predict what they will do, but I believe they should definitely do that. I would say that they scored your bill, S. 2605. That does not have mandatory bidding; that has a system of guessing what the companies are going to do and what the prices would be after there were a bidding process.

I would submit that if you could prove everything you would not need actuaries. That is what actuaries are for; they are supposed to be based on common sense and a lot of data. They are supposed to be able to tell you what most probably will happen.

The Medicaid market, I think Mr. Schondelmeyer said, was 13 percent. That is consistent with our numbers. We are somewhere between 10 and 15 percent of any company in the Medicaid market. That is such a small part of the market that if the companies are given a market-driven best price, they are not apt to be able to change that market-driven best price which covers 90 percent of the market in order somehow to gain the 10 percent.

In other words, the dog is the HMOs, the hospitals, the other people that are out in the marketplace; while the tail is the Medicaid program. I do not think that an actuary would have to go very far to say the tail is not going to wag the dog.

Senator Pryor. Has the PMA suggested legislation along the lines of an effort to bring Medicaid prices down?

Mr. Mossinghoff. The PMA, as such, has not. At our last Executive Committee meeting, the Executive Committee noted what was happening among the dozen or so companies. They noted with approval that what was happening was providing automatic access to drugs in return for discounts and rebates.

I do not know if my general counsel will let me do this, but I think it is a safe thing to say that 12 or 13 companies are reported to be active in the field. I suspect there may be more that are not reporting it, and that the numbers will grow throughout the industry.

Senator Pryor. Well I do not know whether your lawyer will let you answer this question either. But let me ask, and if it is some sort of a disclosure you would not like to make, I would understand that. How many companies belong to the Pharmaceutical Manufacturers Association?

Mr. Mossinghoff. Really there are over 100 separate corporate entities. Counting subsidiaries, it really comes down to about 60.

Senator Pryor. So you have now 5, 6, or 7 companies out of the 60 recognizing that prices in the Medicaid program have been too high and basically saying we are going to make that better. Now how long will it take the other companies to come along?

Mr. Mossinghoff. Well, it is really now about a dozen companies, and they are the biggest companies. They are the ones that are represented on our Board—a Board of about 30 people. So I think it is probably—in terms of the major pharmaceutical houses—about a dozen out of 30.

Senator Pryor. Did this dozen companies begin this negotiation or suddenly wake up and see these prices were too high as a result of S. 2605 and companion bills or was this something they were going to do anyway?

Mr. Mossinghoff. I do not know the answer to that, Mr. Chairman.

Senator Pryor. I think I know the answer.

Mr. Mossinghoff. I do know that your bill basically came out of the hearing last July. So I do not have any reason to say that it would have been done without that political pressure.

Senator Pryor. You know we had Senator Hatch, our friend and colleague earlier this morning and he had come from the Souter hearing. I watched Judge Souter the other night. I got hooked. I am not on the Judiciary Committee. But I got hooked on watching him do combat with the members of the Committee. I think he did a very splendid job.

One thing he did say about Federal involvement I thought was very succinct. He said that Federal involvement generally only comes—and this has been true for 200 years—when the States or the local governments, or local people, or what have you, do not do something. We do it as a court of last resort.

That is why we are having to do this. This is the court of last resort because there is a feeling that the drug manufacturers are frankly not going to negotiate the best price for the program. There is also a feeling that the drug manufacturers in the past, if past is prologue—we have seen in the past, and it may be in the future—they are going to take advantage. They are going to take advantage of the poorest of the poor in our country, of States strapped for resources and not having the leverage, not having the leverage to negotiate with the pharmaceutical manufacturers.

I think that is one of the reasons, another reason that we are here today. I would hate to call it distrust. I guess I would say nonbelief that the manufacturers are going to come forward.

Now you have characterized—I think you have something a little bit confused here. Back some months ago the OMB, looking for cost savings, there was a proposal by OMB—and once again it is the subject of the budget negotiations at Andrews Air Force Base—OMB came out with a proposal to save some $1.5 billion over 5 years for the Medicaid programs. The OMB did allow the pharmacist to substitute one kind of drug for another without getting the doctor's permission. That is what OMB did.

You have characterized, and your organization has characterized, and put out to many, many health organizations throughout America that my original legislation, S. 2605 was a therapeutic substitution bill.

Mr. Mossinghoff, I can tell you that at every stage of the prescription process we made certain that the doctor was in total control of what that patient was ultimately going to receive. The doctor only had to do a simple thing, that this is medically necessary. So my S. 2605 is a long way from anything called a "therapeutic substitution philosophy."

Mr. MOSSINGHOFF. Senator, I agree with that. We are a fairly large organization, but I can tell you that as soon as S. 2605 was introduced I went personally to great pains and my senior staff went to great pains to draw a sharp distinction between that and some earlier ideas that had been published in the trade press of what you had in mind.

I made it a point in my appearance with some of your key staff people before the American Medical Association's Legislative Council in Chicago to make sure that this was not therapeutic substitution, that you did not have therapeutic substitution. We oppose the call-back system as I have said in our statement. We oppose the three-day supply as I have said in our statement.

There was a lot about S. 2605 that we did not like. But we—my senior staff and I—did not characterize that as therapeutic substitution. It is a restricted list, to be sure. Once you had a list of preferred drugs—based on some national P&T Committee—we characterized that, and I think I would submit accurately, as a restricted list in Medicaid. But we did not characterize it as therapeutic substitution. I drew that distinction as soon as it was introduced.

Senator PRYOR. Well, Mr. Mossinghoff, someone has been characterizing this as a therapeutic substitution bill. I have recently, for example, received a letter from Alzheimer Association, sent to the pharmaceutical manufacturers, and in that letter the Alzheimer Association asked that PMA set the record straight about the position of the association relative to S. 2605.

We have a PMA developed list here of organizations that you claim oppose my bill that have in reality never taken a position on it. This includes the American Medical Association, the American Diabetes Association, the Epilepsy Foundation, AHSP, ASCP, and others.

I wonder if you are willing to set the record straight as to who is endorsing this bill and who is opposing it.

Mr. Mossinghoff. Mr. Chairman, we put out three volumes—the three volumes that Senator Hatch had with him at this hearing—of organizations that spoke out in opposition either to restricted lists or to therapeutic substitution. That was the title of the cover sheet—"Leading Organizations Speak Out in Opposition to Restricted Drug List/Therapeutic Substitution." Maybe the title does not read "and/or" as the people in our Communications Branch wanted it to be.

Let the letters speak for themselves. When I write a letter for PMA, I do not want people necessarily characterizing what I say. I want them to give you the letter. If they want you to know what I am saying, I want them to give you the letter. That is what we did. We sent it to the Senate Finance Committee and to the Energy and Commerce Committee. Those letters are simply named with this cover sheet on the front of them.

We did not say they are all against your bill or all against the OMB proposal. Clearly the Alzheimer Foundation, I think, ends with a statement saying, "We therefore reject the OMB proposal." So we included them in this list.

Since then I have asked our General Counsel's office to review all of them and group them, whether they were against therapeutic substitution or against restrictive lists. In my submissions to the Committee, that is what we attempted to do. But I would urge that the letters themselves speak for themselves and that is the way it should be.

Senator Pryor. I am not saying that you have misrepresented, but I am saying that you have used the names of some very fine organizations where you say have come out in opposition to this bill. If they oppose it, that is fine. But if they do not oppose it, I think you have taken a liberty that you should not have done.

Mr. Mossinghoff. Well I hope not, Mr. Chairman. I hope that you do not think that. Because clearly in the case of the AMA, we were very interested in what they did because of their obvious interest and their obvious persuasiveness in this issue. I know they did not oppose S. 2605. I was there in Chicago when they did not support it. They had some problems with it. They did say that if any parts of that bill immediately got into the budget reconciliation they would oppose it; and they did oppose the OMB naked therapeutic substitution proposal.

Senator Pryor. And I understand OMB now has taken out that part of their proposal. Maybe I am misrepresenting. I thought that. Maybe I am wrong.

Mr. Mossinghoff. I do not know the answer to that. The last time we talked to a key staff person in Senate Finance the answer was that they recognize that there is enough vigorous opposition that it is not going anywhere. But still the only formal piece of paper, I believe, on the table at Andrews Air Force Base, is the June 20, 1990 OMB submission which is naked therapeutic substitution.

Senator Pryor. Mr. Mossinghoff, let me yield to Senator Breaux if I might at this point, and then to Senator Chafee.

Senator BREAUX. I just have a couple of questions, Mr. Chairman. Thank you very much; and gentlemen on the panel, thank you for your appearance too.

I represent one of the poorest States in the country probably with the highest unemployment, Medicare—the Federal Government probably pays over 70 percent of the Medicaid payments in Louisiana. When I look at that and look at a State that is having those types of problems in Louisiana and have to report back that the Federal Government is paying 87 cents for Feldene and my State is helping to pay $1.68 for the same product, I cannot tell them it is because "Johnny came marching home" is something you wanted to take care of.

I mean there is no rationale for doing something good for the veterans and yet the poorest of the poor are being gouged. If that is a fair price for the veterans why isn't it a fair price for the poorest of the poor and some of the poorer States in the nation. You mentioned that Medicaid is not a centralized system. But that cannot account for 93 percent additional costs merely because of delivery problems.

I mean in plain and simple terms, what do I tell people back home?

Mr. MOSSINGHOFF. I think that's——

Senator BREAUX. That is what I will tell them I guess.

Mr. MOSSINGHOFF. From our point of view I answered a question like this almost identically phrased by Senator Pryor last July, I gave what I thought was an eloquent answer, but it obviously has not persuaded anybody—that is, that there is a free market out there. I think what the Federal Government pays actually is based on a historical anomaly.

The fact is that in overall prescription drug pricing we are incredibly or remarkably when we did the analysis a constant share of gross national product. It turns out that based on the 1967 consumer price index—this is general, this is not just Medicaid—we are now virtually identical. There is a median, slight cross over. But the drugs are virtually the same cost now as they were in 1967. In 1965 drugs generally were at 0.84 percent of GNP. We are now at 0.86 percent of GNP.

So if all the elements of the medical program—the medical delivery program in the United States—were as constant as a percentage of GNP, you would not see this chart that goes through in the year 2000 that medical care goes through 15 percent. Every policy maker in this town and all over the country knows that.

If the other elements of the medical system were as cost effective and as constant as a percentage of GNP you would not have that chart going through 15 percent. It would be down to where it was in 1965.

Now that is not a good answer to someone standing in——

Senator BREAUX. It really is not. I appreciate what you are saying, but you are talking about the cost as a percentage of gross national product. My point is, whatever the costs are, why do we have the differentials between government purchases and the Medicaid program. That is what I do not understand. Whether the costs have all gone down or remain the same or are increased dramatically on the products, it does not justify why there is such a huge differential between volume buyers by the Federal Government and volume buyers under the Medicaid program.

Mr. MOSSINGHOFF. Well it is a different volume, obviously. As I indicated this CEO who must remain nameless tells me that he had not focused on this. He runs a very tight company. He had not focused on this until the issue came up and asked what are we doing. And the answer is, we are giving very deep discounts. I believe it was 55 percent to the Veterans Administration. The question was: Why are we doing that? And the answer was: It is less than 1 percent of our sales. They were willing certainly to continue that very low price—that very deep discount to VA—they had established basically in 1943.

So there is, I think, a rationality to this, particularly when you consider the VA as one of the elements in the equation.

Senator BREAUX. What about when you add the HMOs, doesn't that increase the percentage?

Mr. MOSSINGHOFF. Oh, I think for most of our companies it very definitely would raise the percentage. But I do not know. Again, we, as PMA, stay very far away from pricing and pricing policy as we must. But that is, I think, probably the deepest discount you will find, certainly on average or to the VA. They are deep old prices, and they are out of line with HMOs. They are out of line with hospitals, and they are out of line with sales to warehouses.

Senator BREAUX. Do you have a recommendation as head of the association for what Congress might do in order to bring back some balance in this or are you just going to let the various companies present their recommendations?

Mr. MOSSINGHOFF. At this point, Senator, all of the companies are watching this. The companies here all have specific proposals. They all differ each from the other, and they are available to answer your questions on that. There will be Board consideration very shortly to see what it is that might be done as a PMA organization.

It is like that famous rule in town, though, that where you stand depends on where you sit. I do not know. I really cannot guess whether the PMA is going to have a recommendation or not. But clearly the key companies in PMA not only have recommendations, but they are out pursuing them in the marketplace.

Senator BREAUX. All right.

Mr. Chairman, thank you.

Senator PRYOR. Senator Chafee, we are glad to have you join us this afternoon. Senator Chafee?

OPENING STATEMENT OF HON. JOHN H. CHAFEE, A U.S. SENATOR FROM RHODE ISLAND

Senator CHAFEE. Thank you, Mr. Chairman. Just a couple points I would like to make. One, I do support the concept of offering pharmaceutical products at a reduced price to the State Medicaid program.

Also at the same time, Mr. Chairman, I want to stress that in the pharmaceutical industry, we have an industry that unlike all the rest, or all too many industries, come to us wanting help in a whole series of ways and moaning about international competition.

This is one industry that, thank goodness, is a net surplus gainer for the United States of America in its exports. So, therefore, I think we have to be conscious of that. I do not think we want to come charging in like a bull in a china shop because of what prices are offered to VA or whatever it might be.

We have to realize that they are doing something right in that industry in international competitiveness and we want to be conscious of that.

Now I would like to ask, is it Pfizer—I guess it is Pfizer with the Feldene. What percentage does the VA represent of your market?

Mr. BOWLER. Senator Chafee, I am Ken Bowler with the Pfizer.

Senator CHAFEE. Maybe you have touched on this. Have you touched on this?

Senator PRYOR. No. That is a good question.

Mr. BOWLER. I think it is approximately 1 percent. A small percent—1 percent.

Senator PRYOR. That is the Veterans Administration?

Mr. BOWLER. Yes.

Senator CHAFEE. Now, as I get the argument of the pharmaceutical companies that if this Committee should say, whatever you are offering it, no matter where it is and to what entity, then that lowest price must be matched to the Medicaid. That is a suggestion. I take it your argument is, or the argument of the industry, or perhaps it is of Pfizer, is that you have had this long time relationship—Well, what is your argument? Maybe I should not—— [Laughter.]

Go ahead with your argument.

Mr. BOWLER. Senator, I cannot explain the existing differences. Let me say Pfizer's position is—and we have a proposal that we have drafted to this affect—that we would offer to the Medicaid programs our best price. Generally, that would be the VA price.

So one answer Senator Breaux would give, Pfizer, the manufacturer of Feldene, is proposing that whatever Feldene has sold to the VA, that would be the price in Louisiana to the Medicaid program.

Senator CHAFEE. Well that is very nice. Perhaps Rhode Island will sign up on that program. [Laughter.]

Now let's try Glaxo. [Laughter.]

It is kind of like a prayer meeting. Come on up the sorter's path here.

Mr. INGRAM. Senator Chafee, like our colleagues at Pfizer, the VA represents 1 percent of our business. It does receive a significant discount, much more significant than that we provide to other classes. We, in our proposal, which we have voluntarily come to the table with and have signed a number of States up to that agreement, would treat the Medicaid programs in the same manner that we treat other reimbursement type accounts—like individual practice, associated HMOs, network model HMOs and preferred provider organizations.

I would point out that the discounts in our proposal range up to 20 percent, average 15 percent, and certainly in the opinion of a number of States who have signed those agreements, represents significant cost savings for those States. We think it is the most analogous way to treat the Medicaid programs and we certainly think that it would be unfair to take a 1 percent segment of the market and use that as the barometer, if you will, for this segment of the market when different companies have different discount proposals for that 1 percent savings market.

Senator CHAFEE. Well, I can see that. I can see the argument that you historically might have had sort of a nearly charitable relationship with an entity, whether it is the VA or it might even be a charitable institution, in which you sold a very modest portion of your total product sales have been to this entity. And to then say that all future sales to the Medicaid program, for example, would have to be tied to that lowest price, one of the actions I suppose might be you wouldn't sell it at the lowest price to that entity anymore. So we might we shooting ourselves in the foot.

Well, thank you very much, Mr. Chairman.

How would you describe—Am I repeating? I apologize.

Senator PRYOR. Go right ahead.

Senator CHAFEE. I just arrived back in town.

How would you describe the negotiated sales or the sales you now have to an HMO, for example? What is the term you would use to say you are willing to sell to Medicaid at that, what, negotiated price that you are using to what? How would you phrase it?

Mr. INGRAM. Senator Chafee, we negotiate contracts with these reimbursing HMO customers and we have pledged to give to Medicaid agencies the best price that we give to any of those customers by product.

Senator CHAFEE. The best price would go to all State Medicaids?

Mr. INGRAM. To all State Medicaids, yes.

Senator CHAFEE. The best price that you have achieved within that State or nationally?

Mr. INGRAM. Within nationally, within the whole reimbursing HMO customer segment. I would again say that that segment currently represents just in the IPA model 20 million Americans. Within the preferred provider organization market you have somewhere between 80 million subscribers to PPO services. It is a very competitive segment of the business. In our case it represents in excess of 30 percent of our business and we would submit, Senator Chafee, Senator Pryor, that that segment of the business is one that at least Glaxo would be very reluctant to walk away from; and thus ensure, if you will, those types of discounts for Medicaid programs.

Senator CHAFEE. Okay, fine. Thank you, Mr. Chairman.

Senator PRYOR. Thank you, Senator Chafee. Senator Chafee, this has been a fascinating hearing this morning and we appreciate your being here. Do not feel apologetic if you want to cover some ground that is already covered. Because those areas of question you had were not covered earlier.

Mr. Ingram, could we get the same price in this country that you are selling your drugs to the Europeans for?

Mr. INGRAM. Senator Pryor, I am not familiar with the prices we sell our products in Europe. I would comment that Senator Hatch, I think, this morning pointed out some of the rationale for, if you will, cases where prices are higher here, due to the longer review process at FDA.

Senator PRYOR. Mr. Mossinghoff?

Mr. MOSSINGHOFF. I would respond to that by saying that the European systems of price controls go all over the lot. They are very different.

Senator PRYOR. I know they are very complex.

Mr. MOSSINGHOFF. In some countries, such as the United Kingdom, they do not control prices at all, but they control levels of profit under their health-care system and others. France is a very regulated system. They have among the lowest prices regulated. And among other things they limit the number of pharmacists that can exist by a strict quota. In Sweden they also have price controls. They have no pharmacists in the private sector. They all work for the Government. They all have a socialized pharmacy.

So I would submit that you really cannot look to Europe or any specific country in Europe and come up with anything that would recommend itself to the United States.

I would also point out that exchange rates have an enormous amount to do with this. A hypothetical product introduced in 1981 at $2 all over Europe would differ by 300, 400, 500 percent now just because of exchange rates themselves.

Senator PRYOR. Senator Breaux?

Senator BREAUX. On the line of questioning that we are talking about, I like what I am hearing from the companies. This is the question, and I think Senator Chafee may have referred to it: What is the possibility of us accepting that type of a proposal and just having the affect of it minimized by increasing the prices to every other person that you sell to at the low price? In other words, instead of having the Medicaid price come down, just have all the other prices come up to the cost that we are charging Medicaid for the drugs. There would be no guarantee of that. I guess that is my concern.

Senator Chafee, I think, raised it. Are we just requiring all volume purchasers to have their prices increased to that $1.68 and you can say, well that is our best price; everybody is paying $1.68 now. Is there anything within that mix that would address that particular concern?

Mr. INGRAM. Senator Breaux, I can see where that is an attractive consideration. I can only speak for Glaxo in that, as I said earlier, 30 percent of our business—in fact, over 30 percent—is in that HMO market; and it is a very competitive market.

Senator BREAUX. Competition within the market would require you not to just arbitrarily raise your prices because somebody else could come in and undercut you?

Mr. INGRAM. Right.

Senator BREAUX. Does anybody differ with that?

Mr. BOWLER. Senator, I would offer the same observation. In a statement before Senator Pryor's Committee on Aging, a witness for the Veterans Affairs made some statement that he said, "it was difficult to identify a trend in cost because variables such as competition have a dramatic effect." There are market forces in affect that produce the discounts to VA and others.

We see no basis for assuming those market forces are going to go away. They will continue to operate, continue to produce discounts to the VA and others, and under the Pfizer proposal those discounts will be passed on to Medicaid.

Senator Breaux. Thank you, Mr. Chairman.

Senator Pryor. Gentlemen, a moment ago Senator Breaux made the statement talking about how poor the State of Louisiana was. If he thinks Louisiana is poor, let me say, he "ain't seen nothing yet" until he goes to his northern neighbor Arkansas. Because our Medicaid program—I do not know about Rhode Island—but our Medicaid program is about 50 percent of poverty. That is when you get on Medicaid. That is about $216 a month or something like that. So we are talking about some very poor people.

In our State a Medicaid recipient can only receive six paid for drugs out of the program. Anything over six different drugs that poor recipient has to pay for that drug out of their pocket if they can buy it; and most of the times they cannot.

My question is this: Is there a mentality—and think about this, let's go back ten years—is there a mentality in the drug manufacturing industry? Well the Medicaid program is a Government program. No matter what we charge the Government is going to pay the price. Are you thinking of a Medicaid program being a Government program in that context and forgetting that Medicaid patient out there who many times has to take more than six drugs? Eight, ten drugs is normal I think now. Are we forgetting that individual who cannot, who simply cannot, pay for those extra drugs that they have been prescribed by their physician?

Mr. Mossinghoff. Mr. Chairman?

Senator Pryor. Mr. Mossinghoff?

Mr. Mossinghoff. I would answer generally. I cannot imagine that there was that thinking that this is a Government program. When Congress designed the Medicaid program, which is an optional State program, it chose to go through existing warehousing, distribution, pharmacy systems of dispensing. So the prices that our companies charge are those that they charge the general system.

Now it turns out that somewhere between 10 and 15 percent of that happens to be reimbursed through State systems because of Medicaid. But it is the 85 to 90 percent that I would submit sets the parameters of the basis. Now not knowing how companies individually do it, it just seems to me that they are implementing the congressional decision that I assume was recommended by the administration to be normal: You go to the corner pharmacy or chain store and buy your prescription and that is the price. That is the price that Medicaid pays, and it is the price that anyone else pays.

So I could not imagine there would be that, but I cannot say specifically. Because, one, I was not there; and two, I do not get involved in prices.

Senator Pryor. Well on two occasions today you have mentioned the fact that the cost of prescription drugs, I believe, has been basically running about 1 percent of the GNP. To Senator Breaux you answered that question and in your opening you also made that general statement. That is correct?

Mr. Mossinghoff. Yes, actually 0.86 in 1989.

Senator Pryor. If you are a local pharmacist and you are down in Baton Rogue or Providence, or wherever, Little Rock, and the poor recipient of Medicaid comes in and they are going to have to pay out of their pocket for the cost of drugs, and that poor pharmacist has to face these people almost on a monthly basis to tell them their drugs have gone up again, I think that it would not be wise for the pharmacist to try to explain to that citizen that wait a minute, this is just 1 percent of the GNP.

It is kind of like Senator Breaux said, what am I supposed to tell these people. We do not have a defense for this right now. We do not have a defense for these price increases in prescription drugs. We do not have a defense for the variation of the Medicaid versus the VA and the HMOs and the hospitals. That, to a degree, is what we are about today.

Dr. Zabriskie, your company, Merck, I have praised you in public and in private for sort of taking the lead, being the first to come out here and say, we are going to start giving our lowest price. I do not think your program is going to cost out by OMB or CBO.

What do you think of—What kind of indexing might you support or might Merck support—cost indexing?

Mr. ZABRISKIE. On Friday, Senator, I talked about a proposal that we have been thinking about. The reason that we got to that situation was because we understood that Government would find it difficult to score anything without some sort of an index. And thinking about it, we thought the Government is trying to ensure a minimum amount of savings. In your bill, for instance, the minimum amount of savings is targeted at at least a minimum discount or rebate of 10 percent.

The argument had been going that if prices increased much faster than the rate of inflation then that savings could be wiped out. So thinking about those two things together and the fact that we needed something that could be scoreable, we thought that a fair approach would be a 10 percent across-the-board discount, plus any excess price costs that were generated by price increases greater than the rate of inflation.

So a manufacturer freely in a free market could increase prices as they saw fit, but in doing so they would guarantee that Medicaid would save the amount of money that was originally intended.

Senator PRYOR. Thank you, sir.

Any other comments along that line? [No response.]

Let me at this time if I might yield to Senator Breaux or to Senator Chafee.

Senator CHAFEE. Just a quick question for the record, and perhaps this is already in the record. Maybe it varies. If it does vary by company substantially then perhaps we could have it from the industry spokesman. That is: What are the percentage of sales of your company or the industry to these various entities? In other words, is it accurate to say that for each of you your sales to the VA are 1 percent?

Mr. MOSSINGHOFF. Yes.

Mr. INGRAM. Yes.

Senator CHAFEE. Okay.

Now is it accurate to say that your negotiated sales or competitive bid sales, which are sales to HMOs, are 40 percent? Is that an industry figure?

Dr. COOPER. Ours is 20 percent.

Senator CHAFEE. Could you speak into the microphone, please?

Dr. COOPER. This is Upjohn. Upjohn's would be about 20 percent for the HMOs.

Senator CHAFEE. I think Pfizer said——

Mr. INGRAM. No, Glaxo said.

Senator CHAFEE. Glaxo said it is 40 percent?

Mr. INGRAM. No, over 30 percent. It is 36 percent to be exact, Senator.

Senator CHAFEE. Okay.

Now are there any other big entities that you negotiate with or that you go ahead in a competitive—of course, in the general market, I recognize that—but I am talking to some type of entity that just escapes me at the time that I would not know of. Is there any other similar group?

Mr. INGRAM. Those would be the two groups.

Senator CHAFEE. That would be it—the HMOs and the VA?

How about State hospitals? Don't you get into the same thing as you get into with the VA if that is a——

Mr. INGRAM. Yes.

Mr. BOWLER. There are other Government entities—hospitals—where there are some discounts.

Mr. INGRAM. Right.

Dr. COOPER. State mental health hospitals, for example.

Senator CHAFEE. State mental health hospitals.

Dr. COOPER. Clinics and hospitals.

Senator CHAFEE. And what percentage would that represent of your sales or does that vary widely among the companies?

Mr. INGRAM. Ours would be very small.

Dr. COOPER. Very small.

Senator CHAFEE. One percent, less than 1 percent?

Dr. COOPER. One percent.

Mr. MOSSINGHOFF. Senator, just for the record, in terms of industry-wide sales to VA, I believe, those sales are between 1.7 and 1.8 percent of the entire sole-source market in the United States.

Senator CHAFEE. Now I understand that some companies, such as Merck, it is my understanding, do not discount the HMOs but there are other incentives. Is that correct?

Mr. ZABRISKIE. Our policy has been to—We do not negotiate with HMOs. We have the same price for HMOs as for the regular pharmacy. The main discounts that we do give is to the military and to the VA. We recognize that Merck was a bit different in that regard and that is why we fashioned the phase-in period in our proposal with maximum discounts of 15, 20 and 25 percent over 5 years. And also why we put in our proposal a minimum discount of at least 10 percent.

Senator CHAFEE. Well, I understand each of you have offered proposals on this and I think you should be congratulated for that. We are used to dealing with many, many companies that come forward. I am not talking about this particular area, but all of us are used to sitting on this or other Committees where the companies come in and pretty much stonewall us on our efforts to try and find a solution. So, I want to thank each of you for what you have offered here, and I look forward to reviewing it.

Thank you, Mr. Chairman.

Senator PRYOR. Thank you, Senator Chafee.

One quick line of questioning right quick and then we will go to our next panel. Mr. Mossinghoff, you have been very smart I think in something you have done over the last several months, that is put out a series of advertisements in the Washington Post and Roll Call newspaper, other famous publications.

Mr. MOSSINGHOFF. The Senator who suggested that would not readily come to your mind, that was Senator Metzenbaum who suggested we do that.

Senator PRYOR. Well you did it. What it does, basically, the bottom line in all these very expensive advertisements, in my opinion, is sort of justify your big profits and price increases over the last decade. But that is my opinion and you have yours.

Now Congressman Stark had a little takeoff on your advertising program. Have you seen Congressman Stark's little takeoff here?

Mr. MOSSINGHOFF. Unfortunately, yes. [Laughter.]

Senator PRYOR. Well it says, "Drug industry advertising and research budgets running neck and neck." Is that correct?

Mr. MOSSINGHOFF. The only data we have on that, and it actually comes from a hearing that Chairman Waxman held over on the House side, and with some variation his conclusion was that the amount spent on promotion, education, continuing medical education and so on was about the same as research with one higher than the other in some years and lower than the others in some years.

It certainly is not the three to one ratio that we have heard. It is certainly about one to one. It is one of the services—and I think you will find a lot of medical doctors agree with that—that the brand-name industry provides over the generic industry. When a new drug comes on the market, it is potent. While it has great beneficial effects, it also has a lot of potency to it, and there is a lot of information that flows to doctors, to very busy, hassled doctors. There is a lot of information flowing from our detail personnel and the promotional materials.

Senator PRYOR. Mr. Mossinghoff, one of these ads mentions the amount of money spent in research—research and development of new drugs. In fact, all of them sort of refer to that. It is interesting that your association does not also say that the industry gets big write-offs for research and development, tax breaks. Do you think that tax breaks are fair? Should they be increased or decreased?

Mr. MOSSINGHOFF. Well we certainly are in favor of retention of the R&D increase, which I would not characterize as a big write-off. It is, I believe, a 20 percent tax credit for the additive, the delta. It is not this year's research that is the base; it is the amount that this year's research exceeds last year's research cost. I believe it is 20 percent for the R&D tax credit. We think that is very fair. It certainly is a very small percentage of what we spend on research.

Senator PRYOR. Senator Breaux?

Senator BREAUX. No questions.

Senator PRYOR. Senator Chafee, any further questions for this panel?

Senator CHAFEE. No questions.

Senator PRYOR. We want to thank you, Mr. Mossinghoff, and your colleagues in the drug industry. I thank you for coming and we will go to our next panel. Thank you very much.

Our next panel, ladies and gentlemen, will—by the way, I just started to announce for my colleagues and the audience's information that I was planning to proceed through the noon hour. It is now 1:20. I guess we are through the noon hour. So we will keep going. We have two more panels.

We have Marsha Simon, Legislative Director, Families USA; Nancy Dickey, M.D., Member, Board of Trustees, American Medical Association; and James Cloyd, Doctor of Pharmacy, Associate Professor, Head of the Department of Pharmacy Practice, University of Minnesota.

We look forward to this panel. We will try to abide by the five-minute rule. We thank you for your patience. Now, Marsha Simon, we will appreciate your comments.

STATEMENT OF MARSHA SIMON, LEGISLATIVE DIRECTOR, FAMILIES USA, WASHINGTON, DC

Ms. Simon. Thank you for the opportunity to testify on S. 3029. Families USA supports this bill because it promises to control excessive inflation in Medicaid drug cost as well as to increase access to needed prescription drugs for the very poor. This is especially important for elderly Medicaid beneficiaries who use three and one half times as many prescription drugs as other Medicaid beneficiaries. It is essential to assure that the Medicaid program is getting its worth.

Prescription drugs, according to the Federal Funds Information Service, are projected to cost Medicaid approximately $3 billion next year. Medicaid prescription drug payments from 1973 through 1985 rose at an annual rate of 11.8 percent with only one-fifth of this increase accounted for by increased use of drugs. States are struggling to pay these staggering increases.

As a result, in many States Medicaid beneficiaries cannot get the medicines they need because of State-imposed restrictions. In 1986 48 States covered drugs in their Medicaid programs. Of those States 22 charged co-payments to beneficiaries, 11 States arbitrarily limited the number of prescriptions per month, 19 States excluded coverage of entire classes of drugs without physician override provisions such as prior approval. The situation continues to deteriorate.

For example, Oklahoma this year cut back its program from four to three drug prescriptions per month. South Carolina is right now considering dropping from three to one prescription per month.

Senator Chafee. Excuse me. When you say a prescription, is that for a—A prescription is just one drug?

Ms. Simon. That is right. And without regard for whether the beneficiary needs three prescriptions or six drugs, they are arbitrarily limited to as few as one prescription per month in some States.

Senator Chafee. Okay. Now would that prescription cover the balance of the month in theory? Would it be a prescription of adequate drugs for a month? Is that generally the technique?

Ms. Simon. It depends on the States. Typically that would be correct. Many States only permit the dispensing of one month's amount of a prescription. That would be standard practice.

Senator CHAFEE. Thank you. Go ahead. Thank you very much.

Ms. SIMON. These kinds of restrictions are having a harmful effect on the health of Medicaid beneficiaries. A 1987 study of New Hampshire's imposition of a three-prescription limit per month found that Medicaid beneficiaries use 30 percent fewer drugs following the imposition of this restriction. The authors concluded that these Medicaid beneficiaries, especially the elderly, did not get the drugs they needed as a result.

Over the past 5 years some States have sought bids from manufacturers in an effort to lower prices. Until Senator Pryor's legislation was first discussed, the drug companies refused to negotiate. Meanwhile, other purchasers such as the Department of Veteran's Affairs, HMOs and hospitals, have been able to negotiate discounts.

This legislation requires States that cover drugs to make available all medically necessary drugs either through a formulary or a streamlined approval process. The legislation prohibits Medicaid drug programs from arbitrarily excluding any medically necessary drugs.

Some drug manufacturers have only now proposed discounts for State Medicaid programs. But it is important to understand the differences between the discounts proposed by the manufacturers and those proposed by S. 3029. The manufacturer's discounts are for only 1 year with no guarantee that these discounts will be offered again.

Since none of these proposals index prices savings could be wiped out by inflation. In addition, the manufacturers have not proposed a discount innovator multiple drug source products. That is the original patent brand of a product that is now a multiple source drug. Medicaid incurs significant expenditures for these products.

S. 3029 would not be time limited, would index drug prices to the CPI, and would apply to both single and innovator multiple drug source products. S. 3029 will save the Federal Government an estimated $2.5 billion over 5 years. We believe that these savings should be used to help the Medicaid program address high priority unmet needs.

One current initiative before the Congress that could be funded from these savings is S. 1942, the Medicaid Home and Community Care Options Act. Mr. Chairman, this bill represents a rare opportunity to achieve savings and improve quality of care in the Medicaid program. We urge the Committee to adopt this legislation and to reinvest the savings in new health and long- term care initiatives.

Thank you.

[The prepared statement of Ms. Simon appears in the appendix.]

Senator CHAFEE. All right. The next witness, Dr. Dickey.

STATEMENT OF NANCY W. DICKEY, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, RICHMOND, TX

Dr. DICKEY. Thank you. We appreciate the opportunity, Mr. Chairman. My name is Nancy Dickey. I am a family physician in Richmond, Texas, and a member of the AMA Board of Trustees. The American Medical Association appreciate the opportunity to address proposals for the payment of drugs under Medicaid.

Prescription drugs are often the therapy of choice and can be the most cost effective means of treatment. The affordability of prescription drugs directly affects the nature and the quality of care available to our patients. Dramatic increases in the costs of prescription drugs can have a deleterious affect on the access to care and patient compliance with prescribed treatment.

Physicians' concern over the cost of prescription drugs has led our association to call on the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The AMA has also prepared a report on the increases in prescription drug prices during recent years and a copy of that report is included with this statement.

Once Medicaid prescription drug reimbursement was identified as a primary target for cost-cutting and reform there have been a number of proposals introduced to accomplish this. Some of these proposals have the potential to be truly dangerous to Medicaid beneficiaries and we strongly oppose them. Specifically, any Medicaid proposal which relies on the concept of therapeutic substitution should be rejected.

The risk of therapeutic substitution for the patient stems from the fact that individual patients may react differently to a drug for reasons related to their other medical conditions, other drugs they may be taking, and factors such as the patient's age, race and individual sensitivity to the drugs. The AMA expressed strong opposition to a recent OMB proposal which would rely on a therapeutic substitution scheme as a part of deficit reduction efforts.

Another approach to this issue is Senator David Pryor's Pharmaceutical Access and Prudent Purchasing Act of 1990, S. 2605. Senator Pryor has indicated that his primary concern is the increasing cost of drugs under the Medicaid program and the fact that drug costs are detracting from the ability of Medicaid to provide adequate reimbursement and coverage for other needed benefits.

The AMA shares Senator Pryor's concerns regarding the impact of prescription drug prices on Medicaid programs across the States. The AMA has identified in S. 2605, however, several problems which would affect the quality of medical care for Medicaid beneficiaries. The AMA, therefore, does not support the bill as introduced.

Even if this legislation does not go forward, though, Senator Pryor deserves our commendation and appreciation for the extensive work he has done on this issue. He has demonstrated an extraordinary effort to be flexible and to be open to suggestions and concern expressed by the AMA and others. I think we have seen that again today in Senator Pryor's questioning of witnesses. The AMA staff continues to work closely with the staff of the Special Committee on Aging and we appreciate the ability to do so.

Because of Senator Pryor's efforts companies within the pharmaceutical industry also have responded with cost containment proposals of their own. These proposals in general take a straightforward economic approach and do not incorporate those elements such as therapeutic substitution that cause us concern with the quality of patient care for Medicaid beneficiaries.

Just within the last several days Representatives Wyden and Cooper and Senator Pryor have introduced new legislation which at first reading appears to incorporate a drug-pricing approach similar to that proposed by the drug companies. The new legislation does not incorporate therapeutic substitution or therapeutic interchange in any form and appears to address other concerns the AMA has raised with other legislation.

We support the concept of an economic solution such as a drug discount program over other proposals which would affect patient care. However, we have identified several places in the bills where the legislative language does not appear to reflect what we understand to be the intent of the sponsors. We also note considerable differences between the two bills in the important area of drug utilization review. There is no reason why these issues cannot be resolved and the AMA will attempt to do so through Senator Pryor's and Representatives Cooper's and Wyden's staffs.

In conclusion, we are encouraged that the parties to this issue appear to show genuine concern for the quality of care of Medicaid beneficiaries. We also are encouraged by the flexibility demonstrated by the parties to this debate. Certainly the AMA would not support an approach that would result in a diminished or second class level of care for the population served by Medicaid. We are confident that appropriate substantive reform and savings to the Medicaid program can be realized.

We would be happy to answer any questions that you might have.

Senator Pryor. Thank you, Dr. Dickey.

[The prepared statement of Dr. Dickey appears in the appendix.]

Senator Pryor. Dr. Cloyd?

STATEMENT OF JAMES C. CLOYD, PHARM.D., ASSOCIATE PROFESSOR AND HEAD OF THE DEPARTMENT OF PHARMACY PRACTICE, COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA, AND MEMBER, PROFESSIONAL ADVISORY BOARD, EPILEPSY FOUNDATION OF AMERICA, MINNEAPOLIS, MN

Mr. Cloyd. Mr. Chairman, Mr. Chafee, and Mr. Breaux, on behalf of the Epilepsy Foundation of America I thank you for the opportunity to provide testimony. EFA represents more than 2.5 million Americans who have one or more types of epilepsies. On a personal note, I too have a keen interest in this area. My father developed epilepsy as an adult and for 20 years our family lived with this disorder. And were it not for the medication he took daily our life would have been infinitely more stressful.

On a professional note, I have an interest in epilepsy in my conduct of research in this area. I examine the clinical pharmacology of anti-epileptic drugs and as a practitioner I serve as a clinical pharmacist at the Comprehensive Epilepsy Program at the University of Minnesota. My job there is to assist my medical colleagues in assuring safe, effective and economical drug therapy for our patients.

As a background to this testimony I would like to say something about the nature of the epilepsy. It is a complex disorder; and actually represents several disorders. There are many different types of epilepsy requiring many different types of therapies. And, indeed, the patients who have this disorder often react quite differently and markedly differently depending on the medications used in their treatment.

The EFA has great interest in the various Medicaid drug pricing proposals that are now on the table. Bear in mind that drug therapy is the mainstay of treatment for patients with epilepsy. Optimal drug therapy permits more than 80 percent of patients to achieve improved seizure control and a relatively normal lifestyle. However, patients do react differently to various anti-epileptic drugs, even those within the same chemical class. And finally, virtually all the anti-epileptic drugs possess a very narrow therapeutic range—the difference between good seizure control and severe toxicity.

With these comments in mind let us go on to say that we are generally supportive of the proposals embodied in S. 3029. We applaud the effort to reduce cost and the effort to improve quality of drug therapy, a point which has not been raised in these discussions, but one which we think is very, very important in the legislative proposal.

However, we do have some concerns. With regard to substitution of one drug in a chemical class for another there are simply too few medications and patients react too variedly to permit therapeutic substitution. For this reason, EFA opposes such legislation in whatever proposal is on the table.

With regard to accessibility, particularly that embodied in S. 3029, we are supportive of open access through the rebate program. We would oppose any legislation which contains language that would require preapproval of any drug manufactured by a company participating in the rebate program. We would prefer to see that all drugs of a company in a participating program be made available to patients.

With regard to prior authorization, we feel that should such an authorization be required there needs to be a timely appeal process, that in the interim patients should be provided a limited supply of drug until the appeal is settled; and finally, that language should be provided that provides for an acceptable rationale for denial if denial is so issued.

With regard to drugs from a multiple source that have a very narrow therapeutic range, EFA is opposed to limiting access to drugs in that group, which includes virtually all the anti- epileptic drugs. Patients taking either the innovative drug or a product from generic company A, B, or C should be permitted to continue taking such medication and not to experience a precipitous change from one manufacturer to another which might result in loss of secure control on toxiety.

Indeed, the very limited cost savings realized by switching from manufacturer to another will be quickly lost because of the increased cost associated with monitoring drug therapy when one changes from one manufacturer to another.

Finally, we wish to comment on "me too" drugs. Much has been discussed about such entities, but we feel that there are value in these kinds of compounds, specifically those which may have similar affect, but a better side affect profile. Likewise, companies that take the step of providing enhancements to formulations, such as sustained release or liquid formulations for the elderly, these two should be recognized and supported.

Finally, we would like to applaud the efforts to provide both prospective and retrospective drug utilization review. It occurs to us that this is a means to improve the drug therapy of the patients most in need of this effort.

In conclusion, EFA strongly urges any legislation reported out of this Committee must ensure the following: (1) Access to all drugs determined to be medically necessary; (2) when necessary, reasonable and efficient prior approval procedures; (3) that overall cost savings be ensured without burdensome administrative processes; (4) that adequate incentives are made available to ensure the continued development of new products and formulations; and (5) finally, that patients receive medical information, including information on the safe and effective use of medications which will help them make better decisions about their health.

Thank you.

Senator PRYOR. Thank you very much, Doctor.

[The prepared statement of Dr. Cloyd appears in the appendix.]

Senator PRYOR. I want to thank all of the panelists today. Let me ask two or three very quick questions because time is running.

Ms. Simon, you are representing Families USA and I want to sincerely thank you and your splendid organization for your support. Do you feel that either of the bills that I have introduced would result in so-called "second class" treatment for Medicaid beneficiaries? This has been claimed by some organizations.

Ms. SIMON. Families USA would like to thank you, Senator, for your leadership on this issue. In answering your question, no, we do not think that it would exacerbate the current situation where, frankly, too many beneficiaries receive second class health care in the Medicaid program. We support both your second and your first bills.

We think it is necessary to recognize that States are going to place restrictions on their drug programs; and we felt that the information on therapeutic equivalents would have been very useful information to State Medicaid programs in making those decisions.

Senator PRYOR. Thank you very much.

Dr. Dickey, I want to thank you and the American Medical Association Board for not only your cooperation but also your flexibility. I know anytime you mention therapeutic substitution there is a great fear. I know it is spine tingling to physicians. I can understand this and I am sensitive to it.

Now you do not feel that my legislation, S. 2605, is a therapeutic substitution bill; is that correct?

Dr. DICKEY. No. We understand the difference between the therapeutic interchange and the therapeutic substitution.

Senator PRYOR. Thank you. I wanted to make the record straight on that.

You also indicated that the American Medical Association has basically articulated five criteria of any Medicaid drug pricing legislation. How does, let's say, my new proposal that I introduced Wednesday, how does that proposal meet within that five criteria boundary?

Dr. DICKEY. We support the philosophy of an economic solution to what we consider an economic problem. Our remaining concern is with the language not tracking some of what we understand your intent is. For example, the prior authorization provision. Senator Bradley this morning alluded to the problems of very busy physicians. I might need to add a second waiting room where people would line up waiting for answers to their preauthorization problems. We appreciate your willingness to continue to work on that language to be sure that your intent and the language track one another.

We also have concerns with the S. 3029 drug utilization review provisions. Again, we support the concept, but want to assure ourselves that the primary goal of DURis to improve the quality of care and not to set up a back door for a restrictive formulary or a cost-control mechanism.

Senator PRYOR. Very good. Thank you.

A final question for Dr. Dickey. A philosophical question, Doctor. Should the Congress proceed with believing that there is hope for a voluntary approach by the pharmaceutical manufacturers in dealing with the States or should there be Federal legislation?

Dr. DICKEY. As we have stated, the AMA has a broad plan for Medicaid reform. In order to be able to address the needs of more beneficiaries and increase Medicaid coverage we have to find some savings. So with that in mind, I think our concern with the voluntary approach is something which you have also expressed.

The voluntary approach is not indexed over time. There is no guarantee that initial savings will be maintained. Another shortcoming of all the voluntary industry proposals that we have reviewed is that they do not address the issue of how to achieve access for our patients to those drugs that are not part of the voluntary repate program. But we are delighted that we are seeing some flexibility and willingness for everyone to sit at the table and try to work out the solution through legislation or otherwise.

Senator PRYOR. Dr. Dickey, thank you.

Senator Breaux or Senator Chafee?

Senator BREAUX. I just have one quick question, Mr. Chairman, if I might to Dr. Cloyd.

You raised a point that Senator Pryor's bill would only reimburse pharmacists for disbursing preferred drugs unless the physician has issued the restrictive prescription for a non- preferred drug. I guess you are expressing a concern that this could be burdensome and time-consuming and create problems.

My understanding of how it would work would just be that the physician in writing a prescription would just indicate the medical necessity for this particular type of prescription drug and that would be it. I do not understand where the burden concept or the delay concept that you seem to address comes into play.

Dr. CLOYD. Our intent was to raise a concern about the availability of several products within a multi-source drug group in which the drug has a narrow therapeutic range. With respect to anti-epileptic drugs it might be a drug such as Carmezapine or Phenytoin or Valproic Acid. And in those cases our concern is that there be relatively easy and efficient continuation of therapy with the initial product.

So if a patient started out on say the brand formulation of phenytoin, Dilantin, that regardless of what the system does, the patient continues to stay on the same formulation. If the patient starts out on generic drug A, that the system would allow continuation of that particular formulation, regardless of bidding and preferred price, et cetera. The change over from one product to another in and of itself is costly with the necessary monitoring and might evaporate any savings achieved by purchasing the lowest cost multi-source drug.

Senator BREAUX. But would not the doctor have the authority under Senator Pryor's bill to indicate that that treatment is the preferred treatment, that it is the treatment that is medically necessary and, therefore, just continue with what you would like to see happen?

Dr. CLOYD. My reading is that that is the case, with the language of I believe both bills if I am not mistaken.

Senator BREAUX. Thank you very much. I thank all the panel members.

Senator PRYOR. Thank you, Doctor.

Senator Chafee?

Senator CHAFEE. Thank you, Mr. Chairman.

Dr. Dickey, on page 5 you mentioned toward the bottom there that you have several conceptual and practical problems with S. 2605, especially with the concept of drug interchangeability and the administrative process. Have you outlined those concerns in more detail in your statement? Or have they been overcome by subsequent introductions?

Dr. DICKEY. Most of our concerns have been overcome with the introduction of subsequent legislation. I would be happy to share some of them with you if you would like.

Senator CHAFEE. Well why don't you just go through them quickly, if you would, and we can, if need be, contact you for further detail? In other words, I am curious what—you set forth objections but you do not specify them. Why don't you go into that briefly?

Dr. DICKEY. Dr. Cloyd, for example, just referred to one of those. That is, in the interchange program on an annual basis a preferred drug in a therapeutic interchange group would be chosen. And while these days are for similar indications there are some diseases that require a very narrow range of response. Therefore, if in January the preferred drug changed from Drug A to Drug B and physicians did not have the opportunity to restrict the prescription, we would find in January that a number of patients with chronic diseases would have to come in and have their disease restabilized, because of the minor variations that can occur even between very similar drugs.

Another concern we have with S. 2605 is the 72-hour rule. That is, providing a patient with a small amount of medication long enough for the pharmacist to attempt to reach the physician to discuss possible interchange. I take care of a fair number of Medicaid beneficiaries. If I can get them to the pharmacy once to fill their prescription then they make take that medication. If I have to get them to the pharmacy two or more times to get the same amount of medication, I run great risks that they will not make the second trip back, will not understand that they have a limited supply and need the second trip back, and, indeed, may be confused if we decide to make a change to another drug and a different drug is dispensed later.

Senator CHAFEE. Well, Mr. Cloyd touched on that same problem in his full testimony as I read it over.

Dr. DICKEY. Yes. So these are things that have primarily disappeared from the new legislation and for that we are very grateful.

Senator CHAFEE. All right. Fine. Thank you.

Thank you.

Senator PRYOR. Thank you, Senator Chafee. Any form of final questions from Senator Breaux?

Senator BREAUX. No questions, Mr. Chairman.

Senator PRYOR. We want to thank this panel. We will now call our final panel.

Mr. Jim Parks; Mr. John Gans; State Representative Alphonse Jackson; and Senator Chet Brooks. Mr. Jim Parks is Chief of the Medi-Cal Drug Discount Program, Department of Health Services, States of California; John Gans, Executive Vice President of the American Pharmaceutical Association; Alphonse Jackson is a Louisiana State Representative; he is also the Chairman of the House Health and Welfare Committee in the Louisiana State Legislature. He is testifying today, by the way, on behalf of the Louisiana Legislative Black Caucus. And we have Texas State Senator Chet Brooks, who is Chairman of the Health and Human Services Committee, Texas State Senate.

Mr. Parks, we will hear from you first and we appreciate all of you being with us today.

Mr. PARKS. Senator, it is a pleasure.

Senator PRYOR. Have I missed someone? I see five of you and I only read four names.

Mr. GANS. Mr. Chairman, joining me is Louis Sesti, the Chief Executive Officer of the Michigan Pharmacists Association.

Senator PRYOR. Very good. Thank you. We welcome you here.

All right. Mr. Parks, we will hear from you first.

Mr. PARKS. Thank you for the opportunity.

Senator PRYOR. Tell us what is going on in California.

Mr. PARKS. I would be happy to.

Senator PRYOR. We will invoke the five-minute rule. Thank you. Maybe that ought to be 35 minutes. [Laughter.]

Mr. PARKS. I will actually do my best to be brief. There are a couple of points that I think I will need to highlight and emphasize.

Senator PRYOR. Sure. Your full statement will be placed in the record.

STATEMENT OF JIM PARKS, CHIEF, MEDI-CAL DRUG DISCOUNT PROGRAM, DEPARTMENT OF HEALTH SERVICES, STATE OF CALIFORNIA, SACRAMENTO, CA

Mr. PARKS. Briefly, I would like to start off by indicating that California supports the concept of Federal legislation to ensure that States with drug discount programs already in place have continued success; and that all States, not just large States with formularies, obtain rebates from manufacturers.

The status of the California Drug Discount Program is as follows: To date we have signed four contracts with manufacturers. Those manufacturers are Merck, Sharp and Dome, Glaxo, GD Serial and Syntex Corporation. We have reached agreements with three additional manufacturers, but the contracts have not yet been signed. We have three formal negotiations scheduled; and we have four informal discussions that have been held which we anticipate will probably lead to formal negotiations.

State law prohibits us from talking about the details of specific contracts, but I will give you some general direction about where we are heading. As a matter of policy, in our contracts, we sign contracts with companies, we do not adopt their national policies. Accordingly, not all of a manufacturer's drugs may necessarily be added to our list of contract drugs as a result of a contract, nor will we necessarily agree to lifting utilization controls or prior authorization requirements for drugs that are placed on that list of contract drugs.

We also in our contracts assure that Medi-Cal retains their prior approval authority to impose those utilization controls in current and potentially future situations. And finally, we assure in our contracts that the savings that are achieved at the point where we reach agreement continue and are not eroded by future price increases beyond agreed upon limits.

California's success to date I think is due largely to several factors. Most importantly in our mind is the fact that manufacturers are concerned about the potential for Federal legislation and they have a desire to obviate the need or preempt the need for such legislation.

Second, Medi-Cal uses both a formulary and utilization controls in our administration of our pharmaceutical benefits program.

Third, Medi-Cal is viewed both in itself as a potentially large direct market with over 3.5 million beneficiaries and represents access to a larger California market.

And finally, some manufacturers now see contracting with us as an opportunity to have their drugs added to our list of contract drugs on a more expeditious basis than was previously available.

In regards to Federal legislation, we see several things that will result in significant savings and those should include a minimum level aggregate savings reimbursement requirement, allowing States to retain their formularies and utilization controls where they exist, and giving States the option of either contracting directly with manufacturers or becoming part of a contracting consortium at the State or the Federal level.

There are, however, in our review of some proposals at the Federal level aspects which we believe have the potential for significantly increasing costs. One of those is a requirement that States have open formularies without utilization restrictions. California has used a formulary since its inception of the pharmaceutical benefits program in Medi-Cal approximately 25 years ago.

We believe that a formulary represents a cost-effective alternative for assuring the appropriate provision of medically necessary pharmaceuticals. The utilization controls that we establish are related primarily to assure that abuse of drugs does not occur or to assure that the appropriate use of drug occurs to prevent unnecessary utilization and cost.

We have estimated that elimination of our formulary would cost approximately $400 million in California alone. That is a substantial cost increase for us, not a cost savings. We view with some concern requirements for the establishment of prospective and retrospective drug utilization review systems.

We are concerned about potential increases in pharmacy reimbursement. For example, in our Medi-Cal program every one penny increase in the dispensing fee will result in an additional cost of $300,000. We are also concerned about the creation of new responsibilities which will need to be funded, such as the annual pharmacy cost audit, State drug use review boards, on-line claims processing capabilities, et cetera. The net result if all of these requirements were imposed on States could well be net cost, rather than net savings.

We do not want people, however, to get the impression that we are opposed to the concept. We support the concept and we will continue to work with everyone who will listen to us in assisting you in designing a cost effective program.

We strongly urge four specific things. That States be allowed to retain control of their pharmaceutical programs, their formularies and their utilization controls, so long as they meet appropriate requirements relative to prior approval processes; that studies be conducted of pharmacy cost audits; and that their be demonstration projects on DAR programs prior to imposing them on a statewide basis for all States; and that there be review of the cost benefits associated with encouraging on-line claims processing capabilities.

We believe if these things are done, both States, the Federal Government, and most importantly the Medicaid beneficiaries served by the programs will gain in the process.

Thank you.

[The prepared statement of Mr. Parks appears in the appendix.]

Senator PRYOR. Thank you, Mr. Parks.

Dr. Gans?

STATEMENT OF JOHN A. GANS, PHARM.D., EXECUTIVE VICE PRESIDENT, AMERICAN PHARMACEUTICAL ASSOCIATION, WASHINGTON, DC, ACCOMPANIED BY LOUIS MICHAEL SESTI, CHIEF EXECUTIVE OFFICER, MICHIGAN PHARMACISTS ASSOCIATION

Dr. GANS. Thank you, Mr. Chairman. As I mentioned, accompanying me is Louis Sesti, the Chief Executive Officer of the Michigan Pharmacists Association, because we felt it was critical that we have someone from one of the States that is affected as one of our affiliates. We appreciate the opportunity to be here.

The guiding principle that APhA, the National Professional Society of Pharmacists has followed since our founding in 1852 has been to advocate those activities which enable pharmacists to enhance the care of our patients. Today, up to 20 percent of all hospital admissions can be traced to some type of drug misadventure. We believe the percentage may be even higher in the Medicaid program.

That is why we have found it so troubling to hear some opponents of S. 2605, Senator Pryor's original proposal, call the legislation "second-class" health care, when, in fact, it incorporates time-tested measures that will enhance patient care. Opponents have cited use of therapeutic interchange as a reason to defeat the proposal. We strongly disagree. Therapeutic interchange is not new, nor is it mysterious. It is simply the use of a formulary or drug list to guide therapy; and it happens every day throughout our nation.

In fact, that is why we are here today. The VA and military programs use formulary-based therapeutic interchange and receive significantly discounted prices. Medicaid does not and pays much higher prices. Therapeutic interchange was developed by physicians and pharmacists working together. It requires them to exchange information regarding the patient's needs and available drug therapies and to select the most appropriate medication for the patient.

Medical and pharmacy associations, along with the Joint Commission on Accreditation of Health Care Organizations have developed standards for this practice. In fact, most of you in this room who have received pharmaceutical care in the last ten years from a hospital in the United States, or from a health maintenance organization, have had your therapy developed through the formulary therapeutic interchange process.

This process has now moved to ambulatory care. We ask a rhetorical question: If this system is good enough for your health care, then why is it not good enough for Medicaid recipients? It seems to us that they are currently receiving second-class care. This lack of equal access to the best drug prices, which has been well documented this morning, and has been well documented by your Committee, Senator Pryor, it is important for you to know that this is not only the Medicaid recipients who are being discriminated against.

Those consumers who purchased their medications at America's community pharmacies are also discriminated against because community pharmacies are unable to purchase at the manufacturer's best prices, even when they enter into extremely large volume buying groups to get low prices.

These consumers are your constituents, gentlemen, who write to you complaining about the high cost of drugs in America. We believe the study called for in S. 3029 which would compare the discounted prices some groups pay for drugs. With the prices community pharmacies must pay for the same drugs will clearly demonstrate the extent the discriminatory pricing practices of manufacturers.

We hope that Congress would use this information from the study as you are intending to use in Medicaid to address the inequities also faced by community pharmacy. APhA also strongly supports the drug utilization review as an important element in quality assurance for medication use. DUR programs collate the total pharmaceutical care received by a patient, which is then reviewed by a group of pharmacists and physicians who compare the therapy against national standards.

By identifying problems early a pharmacist can intervene before a patient may experience a drug misadventure which often requires a hospitalization. For every dollar spent in one study, DUR programs save between $3 and $5.

All of this leads to a basic economic question. How can pharmacists be expected to engage in these new programs—therapeutic interchange, DUR—without additional compensation? I would note, Mr. Chairman, that it is well documented that pharmacy practitioner reimbursement has already been cut significantly in recent years, as States and HCFA have sought to control the dramatic increases in drug product costs.

Proposals now before the Committee in Senator Pryor's bills would begin to restore these inequitable cuts in pharmacy reimbursement and to provide pharmacists with the incentives for implementing the cost-saving measures of DUR and therapeutic interchange.

In conclusion, Mr. Chairman, by utilizing the pharmacist and their skills the legislation proposed by you will significantly improve the quality of care while achieving major savings in Medicaid—a win/win for the American taxpayer. We urge the Committee to support efforts in the area of Medicaid drug price reforms and we appreciate this opportunity.

Thank you.

[The prepared statement of Dr. Gans appears in the appendix.]

Senator Pryor. Thank you, Dr. Gans.

I believe our next witness will be State Representative Jackson—Alphonse Jackson—from Louisiana.

Senator Breaux. Mr. Chairman?

Senator Pryor. I am going to allow Senator Breaux to intercede here.

Senator Breaux. I just wanted to add my welcome to that of the Chairman to Representative Jackson. He is a good friend of mine and he is also one of the senior members of the House of Representatives in Louisiana where he chairs the Health and Welfare Committee, a very important Committee in our State; and was really one of the lead authors in an effort the State made a couple of years ago to try and put in a formulary system in Louisiana.

In their opinion it did not work and they came back and eliminated that. His testimony today addresses what happened down there. I am anxious to hear it and look forward to being with Representative Jackson again.

Senator Pryor. Representative Jackson, Senator Breaux is one of the busiest men in Washington. He has sat in this room 4 hours waiting to make those comments. I wanted you to know that. [Laughter.]

We welcome you to the Committee.

STATEMENT OF HON. ALPHONSE JACKSON, CHAIRMAN, HOUSE HEALTH AND WELFARE COMMITTEE, LOUISIANA STATE LEGISLATURE, TESTIFYING ON BEHALF OF THE LOUISIANA LEGISLATIVE BLACK CAUCUS, SHREVEPORT, LA

Representative Jackson. Thank you, Mr. Chairman; and to my Senator, he can be assured that I am going to vote for him. [Laughter.]

I am pleased to be here to represent my colleagues in the Louisiana legislature and to relate some of our experiences. I have served as Chair of the House Committee on Health and Welfare for 12 years and we have been actively involved in the whole health care delivery system. We certainly share the laudable goals of Senator Pryor and the rest of the Members of the U.S. Congress as it relates to reducing health care cost.

But I have some differences as it relates to the two proposals advanced by the Senator and by the OMB proposal that I would like to share with the distinguished members of this panel. So I would like to summarize my reasons for raising questions about these proposals by way of three concerns.

One is that I do not believe that we can reduce overall cost in the health delivery system as it relates to Medicaid recipients by focusing on one aspect of the health delivery system, and that is the cost of pharmaceuticals. Because pharmaceuticals only represent about 7 percent of the overall Medicaid expenditure to our budget. And when we take means and when we programmatically implement schemes that would produce restrictive formularies, from my experience in Louisiana, we found that we had not a reduction in terms of the overall Medicaid costs, but rather than increase in terms of long-term care and acute care, and doctor's visits and emergency room visits.

So I think that when we examine this whole scheme that we are going to have to be very, very careful that we do not end up increasing costs, rather than decreasing costs as it relates to how we propose to dispense pharmaceuticals.

Second, I question some of the programmatic aspects of all three proposals because I think you are going to reduce the number of practitioners in the whole health delivery system as it relates to Medicaid recipients because I do not believe that they are going to engage in the increased amount of administrative details. And the proposals suggested in the last submission by the Senator in my opinion would create an administrative nightmare as it relates to administering the program.

And thusly, we are going to have a reduced number of practitioners as it relates to the Medicaid program. We are hard put in Louisiana now to find doctors and other health care practitioners to participate in the program in some of the areas.

Third, I am concerned with these proposals because I think that they would limit access rather than to increase access, mainly because I think you would decrease the number of practitioners; and second, I do not see how we are going to implement many of these proposals. And thusly, I think that States are going to take the easy way out and implement restrictive formularies. The practical results will be that doctors will do the same thing because they will get in the habit of taking the path of least resistance.

Also, I am opposed to any Federal program that would place severe restrictions on the ability of States to negotiate and implement their own programs. For example, in Louisiana we have a program that is saving the State a considerable amount of money because we have a MAC program and we have MACed over 800 drugs and we save considerable amounts of money by implementing this program.

I think that if we have an overall program that would set forth for some hard and inflexible rules and regulations that we are not going to be able to do that.

Finally, let me summarize by saying that I do not believe that restrictive formularies will be in the best interest. And if we establish by way of these proposals public policies that would implement a restrictive formulary, that we are not going to reduce costs, but we are going to increase costs. This would certainly have deleterious affects on the whole ability of access and ability of doctors to practice medicine as they have been trained to do so.

When we look at some aspects of this program as it relates to requirements on the part of pharmacies to make certain inquiries and to give certain information to patients, I wonder if we are not asking pharmacists to practice medicine.

I think also we have to examine the aspects of the proposals as it relates to mandating increased costs in dispensing fees. And if we are going to examine the whole scheme of reducing costs, and we ought to, I think we have to also look at the enormous profits that pharmacies are realizing from selling generic drugs and not passing those savings on to consumers and to other Medicaid recipients.

[The prepared statement of Representative Jackson appears in the appendix.]

Senator Pryor. Thank you, Representative Jackson.

Senator Chet Brooks?

STATEMENT OF HON. CHET BROOKS, CHAIRMAN, HEALTH AND HUMAN SERVICES COMMITTEE, TEXAS STATE SENATE, PASADENA/GALVESTON, TX

Senator Brooks. Thank you, Mr. Chairman.

Senator Pryor. By the way, Senator Brooks, where is your district?

Senator Brooks. I am in the Texas Gulf Coast—Houston-Galveston.

Senator Pryor. Very good. Thank you, sir.

Senator Brooks. I appreciate that, Mr. Chairman. Senator Breaux, it is good to be here with neighbors.

I want to tell you very briefly about the Texas program. We are about a $3 billion Medicaid program in Texas, serving approximately 1.2 million people. We made major expansions in our Medicaid programs in our last session in 1989. We are now seeing those implemented and we are having to frankly struggle to keep the money funded necessary from the State's part, to really keep those services going and to meet the new needs that we have identified and for which we have now made formal authorization in our program.

I wanted to tell you first of all that I am very encouraged by what I have heard today. I have been with you the same 4 hours that Senator Breaux has been here and I am very much encouraged by the ideas that are being advanced and what I sense to be a willingness of all parties to try to work together to do something about the overall cost of the programs and certainly try to also remember the quality of care and the quality of the ingredients ultimately being prescribed for our Medicaid patients.

I want to comment briefly on the other thing that was mentioned this morning; and that is the fact that 3 million Texans do not have any insurance. They are working poor. They do not qualify for Medicaid. They are out there working, trying to take care of themselves and their families, but they, frankly, do not have any health insurance.

They are over in the indigent care field and that is an area that I have been working on since 1985. That one has a very tremendous cost and we are going to have to do a great deal more, both Federally and in the States to try to respond to that need.

I might mention the evolution of the proposals that are here; and I would also respectfully ask the Chair to allow me to supplement the earlier submission I made to this committee because there are some changes which frankly I think are improvements. I would like to respond from our State's perspective in a future communication to the committee very shortly.

[The prepared statement of Senator Brooks appears in the appendix.]

Senator Brooks. Along the Texas Gulf Coast I think we might, in our vernacular, characterize the changing proposals in this way: As far as the Texas Medicaid program is concerned the first major was kind of a hurricane. Then it was downgraded to a tropical storm when the second one came out. And now what we are all really seeking desperately is to get a good slow two-inch rain. I hope that we will be able to accomplish that for the benefit of our patients, of all of our Medicaid patients we are trying to serve.

I would respectfully urge all working on this issue not to forget your partners. Medicaid sometimes is thought of as a Federal program. It is not purely a Federal program. States pay. In the case of Texas nearly half of the cost of that program is borne by Texas taxpayers. We also have a very healthy share in the Federal diversity go into that program as well. So remember that those of us who in the States are trying to handle these programs and help fund these programs also have a stake in what happens.

I would like to comment very briefly on one other aspect, and that is about access and the availability of providers. We have just gone through a tough time in Texas identifying problems in our failing rural health program. We have hospitals that have closed almost weekly. We now have seen the closure of over 100. We now have many of our 254 counties that do not only not have a hospital, that do not even have a physician.

In an effort to try to get the Medicaid coverage there, because so many of those people are elderly and they are poor, the families are poor, and they rely very heavily on Medicare or Medicaid, we are trying to see whatever we can do to keep access to providers in those areas.

In this last session I authored a bill in conjunction with the only practitioning physician who is a member of the House, Dr. McKinney. I authored a bill to set up an indemnification program for obstetrical services, physicians who are rendering obstetrical services, and also for emergency room coverage and certain others. We hope that that will keep the access and it will hopefully improve the number of providers we have.

So we would not want to see a bureaucratic system of override that would require busy physicians to make some options, sometime not to make that call, and thereby not be able to prescribe what the physician truly felt was the most medically necessary prescription.

Thank you for the opportunity to share our ideas and our experiences with you.

Senator Pryor. Senator, we appreciate you coming to Washington to give that statement. We thank you very much.

Mr. Parks, let me ask you a question here if I might. Are you aware of any situation in which the drug manufacturers have agreed to give rebates without requiring that all of their drugs be placed on the State formulary?

Mr. Parks. I will answer your question circumspectively if I may. Because of the confidentiality provisions of our contract in process, what I will say is to date, collectively, in all of the contracts that we have agreed to, we have not agreed to add all of the manufacturer's single source products onto our list of contract drugs or to remove prior authorization requirements under certain circumstances.

Senator Pryor. In addition to this, have the manufacturers agreed to any type of use controls on these drugs?

Mr. Parks. Generally speaking, yes, they have.

Senator Pryor. Is the negotiation process working?

Mr. Parks. It is working well from our point of view.

Senator Pryor. But no contracts have been signed?

Mr. Parks. We have four contracts that we have signed.

Senator Pryor. Oh, four contracts.

Mr. Parks. Four.

Senator Pryor. I apologize.

Mr. Parks. And three we have agreed to. The signature process is being delayed in terms of just technical interpretation.

Senator Pryor. On those four contracts, what do you think the savings to Medicaid in California will be?

Mr. Parks. We have estimated that the savings of those four contracts—Excuse me for a second while I refer to a piece of information.

Senator Pryor. Yes, sir.

Mr. Parks [continuing]. Will save in terms of rebates approximately $26 million. However, in that same process we have agreed to incurring an additional $25 million in costs because one of the goals of our contracting process is to increase beneficiary access to needed medicines.

We have in that contract process added approximately two drugs that are rated 1–A by FDA, representing significant therapeutic gains. We have also put four additional drugs onto our list of contract drugs to fill what we view as holes in our therapeutic armamentarium of drugs available through the pharmaceutical benefit program.

I would like to also, if I may, take this opportunity to just indicate very clearly that we see contracting as increasing rather than decreasing access to needed medicines by patients in a number of ways.

First of all, we are in many cases adding what we believe are appropriate drug therapies to our formularies. We also in our effort to achieve State legislation are committed to the addition of 28 additional staff to improve our prior approval processing.

Also, I want to point out that California semi-restrictive formulary means that any FDA approved drug is available, either through the formulary or the prior authorization process. We have no arbitrary limits on the number of prescriptions available to beneficiaries in a given month.

Senator PRYOR. Thank you, Mr. Parks.

Let me at this time yield to Senator Breaux for any questions he has of any of the panel members.

Senator BREAUX. I want to thank all the panel also for being with us for most of the day.

I would like to ask Alphonse Jackson, Representative Jackson, you compared or described the situation in Louisiana where the legislature adopted a fairly restrictive formulary system to try and accomplish what we are trying to accomplish on the Federal level. But then the State reversed itself by a 96 to 0 vote in the House, and I think a 34 to 1 vote in the Senate.

Would you tell us why they took that action, why it did not work, and the perception of the State system that you had in place?

Representative JACKSON. I certainly would, Senator. What we found during the period we implemented a restrictive formulary was astounding. One, that what we thought would reduce costs ended up increasing costs because we found individuals staying in the hospital longer; we found more doctor's visits; we found more people ending up in Emergency Rooms. And we found that doctors actually were prescribing three and four drug treatments where they could have used one because they had to use these three drugs to try to get some treatment, modality, for their patient that would give them some relief.

So we found that it just would not work because doctors could not practice medicine in the manner in which they had been trained. That is why we reversed our situation, even at a time when we were incurring a tremendous budget deficit.

Let me hasten to add that the prediction that the drug budget would just shoot out of the top of the roof cost wise did not come about in spite of the fact that we added 30,000 people to the roles.

The actual expenditure for prescription drugs for a Medicaid patient did not exceed the budget amount. In fact, it came in under what we had budgeted because doctors were able to prescribe medicine, single source drugs, that got patients well quicker, kept them out of the hospital, cut down on doctor's visits and kept people out of acute care and long-term care.

Senator BREAUX. I understand Senator Pryor's bill has two features, at least two, but two that I am struck by in his legislation that would be different from the system in Louisiana. One would be the medical necessity provision that would allow a doctor if he feels a particular drug, even though it was not an approved drug, if it was medically necessary for that patient to recover, that he would be able to simply indicate that and they would be able to get that drug.

The second difference, as I understand it, is that unlike the restrictive system in Louisiana, the system that is proposed by Senator Pryor's bill would ensure that every category has a drug on that therapeutic category and would not have blanks in some of the categories of prescription drugs. That every category would have at least one drug that would be listed as a permissible drug.

Would those features as I have attempted to describe them address the concerns or the problems that you experience in the Louisiana program?

Representative JACKSON. No, they would not, Senator. Let me tell you the reason. Let me take your last concern first, where we would have one drug in each category. Let's take arthritis for example. If you have one drug, we find that often times these patients will develop a toxicity for a resistance to a certain drug because of the toxicity that builds up and you need to switch to something else.

We tried that in Louisiana and what we found were horrible results because people ended up in the hospital. They got a crisis because they could not move to the other drug that would get them some results. So I think that all FDA drugs ought to be on the list. I think that doctors ought to be free to write what they want to write and not have to worry or not worry about whether or not this is on the list or not, or whether or not we have to give prior approval. Doctors ought to be free to practice as they have been trained to do so.

Those two features that are in your bill, Senator, as laudable as the goal is, I think we need to address. Because I think that they will construct and implement a program that will limit access and will end up costing additional dollars in terms of the health care delivery system.

Senator BREAUX. One other point, if I may, Mr. Chairman, is: I guess Louisiana probably operates one of the only true charity hospital delivery systems in the nation for indigent people in the State. I was wondering if Representative Jackson could elaborate as to whether our charity hospital systems in the State, do they have a formulary system for when they purchase medicine in the volumes that they do?

Representative JACKSON. Yes, we have. And they get a discount as it relates to pharmaceuticals. But that is one of the concerns that I was raising when we look at how are we going to reduce overall care. Yes, we had a small reduction in terms of overall costs because of these discounts to our system of State hospitals. But the hospital budget went out of the roof during the time that we had a restrictive formulary because it costs $700 a day for one patient to go to the hospital; and it costs $15 for one prescription that would have kept them out of the hospital.

So what we found were escalating hospital costs, escalating doctor's visits, escalating emergency care visits because we restricted the formulary. So I think we ought to have an open formulary and we ought to encourage these research-based companies to engage in negotiations at the State level to convect the savings that I think can come about. But we ought not to institute price controls that would place a hard break on their ability to do research.

Because if we can find a cure, for example, to Alzheimer, if we save 2 days of expenditures, are we going to more than pay for an affect in savings that you are talking about and that OMB is suggesting that can come about by these schemes and proposals that are before you.

Senator **Breaux**. Thank you very much, Alphonse, for your presentation.

Thank you, Mr. Chairman.

Senator **Pryor**. Thank you.

Representative Jackson, thank you. I may have one question in a moment. Certainly, did you want to say something more to Senator Breaux?

Representative **Jackson**. I just wanted to express appreciation to my Senator for assisting me in having the ability to share my views with this distinguished panel.

Senator **Pryor**. I can assure you that your Senator, and this Senator, and many others are trying to find a way to bring the costs of prescription drugs down and not sacrifice the quality of care. That is what we are trying to achieve.

Representative **Jackson**. I applaud you, Senator. I look forward to working with you in reviewing these proposals and seeing if we cannot make suggestions by way of amendments to achieve the goals that you and I share.

Senator **Pryor**. Thank you.

Dr. Gans, a question for you and Mr. Sesti.

Senator **Pryor**. Now you are with the Michigan Pharmacists Association?

Mr. **Sesti**. That is correct, sir.

Senator **Pryor**. All right. I want to know something. I have heard today a time or two or by implication that the only reason that pharmacists are supporting these initiatives is because both of these pieces of legislation I have introduced contain reimbursement provisions for the pharmacists.

Now why are you supporting this? And, Dr. Gans, why are you supporting these two pieces of legislation? And if that is the reasons I would like to know about it. But what are your reasons?

Mr. **Sesti**. Senator, I will go first. There is a bit of brief background. I am here in great part, I believe, because of two or three factors. One of which is the preponderance of third-party prescription coverage or insurance coverage for prescription drugs that exists in the State of Michigan.

Dr. Wilensky mentioned that 60 percent is paid out of pocket is the data across the country, and 40 percent through Medicaid and other insurance services. That is absolutely reversed in Michigan, approach 70/30 if not knocking on 80/20, whereby in some markets 80 percent is covered by Medicaid or some insurance program.

I can take you to Flint, MI, the home of the good Senator, Don Riegle, and show you 90 percent coverage of health care expenditures through insurance or funding mechanisms. So we are sort of a preview of coming attractions for the Senate and I think the APhA wanted to share these insights with the good Committee.

Number two, I was personally at the forefront of the generic drug law, at that fight in the mid-70s, and we were the first country to pass that at the time, a heralded legislation. Much of the discussion that I have heard in the past four, going on five, hours, while the issue not exactly the same, but the professional and economic issues on both sides of the isle are very, very, very close.

In the other aspect of Michigan being in the forefront of negotiated benefits. I wanted to bring that insight to you.

Yes, there are, indeed, as I read both versions of your bill, Senator, economic incentives for the pharmacists in the sense of restitution and retention. If I personally would not join this table, if that was the only reason, in support of your noble efforts, it was not the reason we were there fighting for the generic drug law in 1970 and joining with the UAW, and the Big-3, and the Democratic leadership in the State of Michigan.

It was a combined effort, a combined reason. It is economics, indeed. I would be foolish to say that that does not motivate mankind, personkind.

But number two, and equally so, is the professional role of the pharmacist in providing care to patients at the sight of action. Even better than in the hallowed halls of our State legislature or in Congress, policy that is permissive, we have found—permissive at it relates to the care of patients—when carried to the sight of action, namely at the prescription counter, where the pharmacist, physician, patient, hospital or all nearby can and often will result in cost savings at no sacrifice to patient care.

Dr. Gans. Senator, I think also your bill is a balanced approach. You are asking the pharmacist to do more—drug utilization review, both prospectively and retrospectively. In your one bill, therapeutic interchange, counseling patients. There is significant increase in activities for pharmacists to improve the quality of care and to bring about these savings.

I do not believe your bills, either one, can be effective unless you have the practicing pharmacist's support in America's community pharmacies. And you know very well that with this escalating drug prices on all the charts we have seen here this morning there has been significant cuts by States and HCFA in pharmacy reimbursement.

In fact, one study by the National Association of Chain Drug Stores states that America's community pharmacies are subsidizing Medicaid to the tune of $300 million a year. Now we cannot allow that to continue and be asked to do more. We can bring about significant savings. But I do believe it is going to require some incentives to stimulate pharmacists to do that.

I think your bill is very balanced. You get much more savings for the small amount of increased reimbursement in either bill.

Senator Pryor. I have a chart. I have not used this today and I thought this might be an appropriate point. I have some great chart preparers. [Laughter.]

I think one of our witnesses alluded to big profits by the pharmacies or the pharmacists. Here is 1988. Here are the drug companies and their profits; here are the pharmacies and their profits. This is the Weekly Digest Survey, 1988 data before taxes. And two is Standard and Poor's Industrial Analysis.

So I think this is significant. I have said everywhere that I do not think anyone has a tougher obligation right now than that local pharmacist who is out there having to tell their clientele on a monthly basis that their drugs have gone up again. As I mentioned to Mr. Mossinghoff, to say, oh, it is just 1 percent of the GNP, that does not go very far. I did want to have that chart placed in the record or a facsimile thereof.

[The chart appears in the appendix.]

Senator PRYOR. You know, Senator Brooks, if I might just mention, I have been a State legislator. I know some of the things that you and Representative Jackson are going through. I also have been a Governor many years ago and I know some of the things that the Governors are faced with right now. The Governors and the State legislators throughout the country are attempting to find a way to save some Medicaid dollars and not to have the program cut.

My original philosophy was to keep the quality of care, save the Medicaid dollars, rather than giving it to the manufacturers. Pass those savings on to the States and ultimately the Medicaid consumer, whereby you could have more dollars for the other areas of Medicaid, they being sharply reduced. That is sort of the original intent.

If I might say this, Representative Jackson, and I say this in all due respect—I probably should not even bring this into the hearing—I have been criticized for attempting to create against minorities a second class tier of medicine. I want to assure you that is not the case. That was the furtherest thing from my mind.

In fact, one of the organizations recently put out a publication when they made reference to sort of—if I can have a moment—when this particular organization made reference, I assume to me. I do not know who else they could be talking about. It said, "When mean spirited bigots want to strike at the black underclass restricted formularies are a convenient way to accomplish their goal."

This is from one of the minority groups. I can assure you, sir, that is not what this legislation is all about. It is not what it was intended to be. I really feel very strongly that this has been mischaracterized.

Representative JACKSON. Let me say, Senator, for the record, that your record in Arkansas is very distinguished and that some of my friends there sing your praises high and you receive high marks for them in terms of your ability to be sensitive and to work with all of the people of Arkansas.

So certainly there was no reference on my part to indicate that that was the direction of your legislation. I do not believe that you would be motivated by such a unprofitable and wrong directed direction.

Senator PRYOR. Thank you. This legislation was intended to help.

Representative JACKSON. I understand that. But we know about legislation, Senator, and we all can work to improve it. That is what this hearing is all about.

Senator PRYOR. That is right. I think this has been a very constructive hearing. Our witnesses have come from a broad range of not only philosophical groups, people who have an interest in this whole area, if it is going to be successful, from a long way around the country—all the way from California.

I have made mention actually after Senator Bradley made his statement this morning and expressed two concerns, I made mention at the end of the hearing I would sort of enumerate every worry and every concern and go down and analyze my response to those. I think I am going to save everyone from going through that because we have discussed these concerns as the afternoon and morning have gone forward.

We are going to leave the hearing record open for a 10-day period. There are other members of the committee who have expressed interest in asking some of our panelists, some of our witnesses, particular questions on points; and we will have those questions forwarded to you as soon as we receive those.

Senator Breaux, did you have any final questions?

Senator BREAUX. No.

Senator PRYOR. We would just like once again to thank all of you. Our meeting now stands adjourned.

[Whereupon, the hearing was adjourned at 2:34 p.m.].

APPENDIX

ADDITIONAL MATERIAL SUBMITTED

PREPARED STATEMENT OF M. KENNETH BOWLER

Pfizer's proposed "Medicaid Improved Access to Medicines Act of 1990" addresses two problems of equal importance: the severe budgetary constraints faced by state Medicaid programs and the limited access to prescription drugs faced by many Medicaid recipients. The objectives of the Pfizer proposal are to address both of these problems through a simple and efficient market-based program that provides Medicaid savings, improves beneficiary access to needed prescription drugs, and minimizes new administrative procedures and costs.

Increasing health care expenditures have severely strained the financial resources of state Medicaid programs. The response has been the introduction of a variety of hospital, physician and other provider reimbursement policies aimed at reducing expenditures. Unfortunately, many of these policies have had the undesirable effect of limiting the access of Medicaid patients to needed medical care and reducing the quality of care they receive.

Medicaid recipients should have access to the same level and quality of medical care received by other Americans. Any proposed change in Medicaid reimbursement policies should attempt to reduce existing barriers to care and improve the quality of the services received by the low-income aged, blind and disabled SSI individuals and AFDC families with children who depend on the Medicaid program.

Pfizer's proposal addresses Medicaid's financial problems by extending to the program discounts on prescription drugs generated by the marketplace. Market forces produce significant discounts on prescription drugs to certain entities, the most prominent being the Department of Veterans Affairs. Essentially, under the Pfizer "best price" proposal, these discounts will be made available to state Medicaid programs. Manufacturers will be required to make quarterly "Medicaid Discount Payments" to each state in an amount necessary to ensure that the state Medicaid program receives the best price (highest discount) given any U.S. purchaser.

By assuring that Medicaid receives the best price on single-source prescription drugs, both the states and the Federal Government will achieve substantial cost savings. We anticipate these savings on single-source drugs will be approximately $200 million a year. Furthermore, these savings can be achieved without interfering in the current market system; without artificial price controls or major new administrative structures and regulatory burdens at Federal or state levels. The savings to state Medicaid programs will continue into the future because the market forces that produce the current discounts will continue to operate. There is no basis for assuming that these forces will disappear and that the VA and other entities will not continue to negotiate substantial discounts in the future. We also believe additional Medicaid savings of the same magnitude—approximately $200 million per year—could be achieved through one of several proposed changes in Medicaid reimbursement for multiple-source drugs.

By requiring all state Medicaid programs that cover drugs to have open formularies, the Pfizer proposal addresses the problem that some Medicaid recipients are limited in their access to prescription drugs. States would be required to provide reimbursement for all FDA approved drugs prescribed by a physician, thereby ensuring Medicaid recipients access to appropriate drug therapy. Not only is equal access correct public policy, appropriate and timely drug therapy frequently eliminates the need for expensive hospital and institutional care. The lack of early and the most advanced drug therapy can result in more serious and prolonged illness requiring more expensive hospital, surgical and medical care.

The Pfizer proposal enables states to capture substantial discounts generated in the marketplace. Equally important, under this proposal, the most advanced and appropriate prescription drugs will be accessible to Medicaid patients.

SUMMARY OF THE MEDICAID IMPROVED ACCESS TO MEDICINES ACT OF 1990

1. *Sole Source Drugs—Open Medicaid Formularies and Manufacturer's Best Price:* Effective October 1, 1992— State Medicaid programs that cover prescription drugs will be required to provide reimbursement for all sole source prescription drugs and biologicals, for any indication recognized in an authoritative compendium and without any requirement for prior authorization.

In order to have their drugs reimbursed, manufacturers of sole source drugs will be required to provide each State a Medicaid discount payment in an amount necessary to ensure that the State receives the best price given any U.S. purchaser.

2. *Definitions:* A Medicaid discount payment is the difference between the manufacturer's price to wholesalers, minus customary prompt payment discounts, and the manufacturer' s best price.

The *best price* is the lowest price charged by a manufacturer to any wholesaler, retailer, provider or government unit taking into account all free goods other than samples, and all discounts, rebates or credits except prompt payment discounts.

3. *Quarterly Medicaid Discount Payments:* States will be required to provide each manufacturer with quarterly information on the utilization of the manufacturer's sole source drugs necessary to calculate the Medicaid discount payment. Within ninety days of receipt of the state utilization data, the manufacturer will calculate the Medicaid discount payment and remit it to the state. The calculation of the Medicaid discount payment will be subject to audit by a mutually agreed upon independent auditor at the state's expense.

4. *No Federal Formulary:* The Federal Government will be prohibited from withholding Federal financial participation, or from requiring states to exclude from coverage or deny payment, for any specific prescription drug or biological, or for any specific class or use of such drug or biological.

5. *Transition Provisions:* In any state that provides reimbursement for all sole source drugs and biologicals of a manufacturer, such manufacturer will be required to make a payment equal to one-third of the Medicaid discount payment for the period from enactment to October 1, 1991, and for two-thirds of the Medicaid discount payment for the period from October 1, 1991 to October 1, 1992.

[6. *Multiple Source Drugs:* Possible options for including multiple source drugs in the legislation include: codify the current HCFA regulations (150% of the lowest priced drug product); use the same "best price" formula as proposed for sole source drugs; or, competitive bidding.]

Prepared Statement of Chet Brooks

Thank you, Mr. Chairman and members of this distinguished Committee for the opportunity to appear before you today and share my perspective on the Medicaid Prescription Drug Pricing proposals under consideration.

For the past 17 years, I have chaired the Texas Senate Committee on Health and Human Services. In this capacity, I have reviewed numerous state initiatives which would affect the health and well-being of fellow Texans. As a member of the Senate Finance Committee and the Legislative Budget Board, I also am quite familiar with the ever-increasing costs of the Medicaid program and the strain this places on state and Federal budgets.

Very briefly, let me describe the current fiscal problems Texas is facing with respect to health care costs under Medicaid. I think this will help illustrate our genuine concern and desire to participate with you in the cooperative development of effective cost-containment measures.

In June of this year, our state legislature passed a tax bill to provide supplemental appropriations for education and health care. Due to unanticipated caseload growth and rising benefit costs, the Texas Department of Human Services had a shortfall of about $200 million in the Medicaid program during State Fiscal Year 1990. The agency is now projecting a shortfall in the program of approximately $630 million for the current fiscal year which began September 1.

These figures alone are staggering, but our state's Medicaid costs are estimated to increase by as much as $3 billion by 1993. Keeping pace with expanding caseloads and escalating benefit costs present a tremendous challenge for state legislatures all across he nation. And quite frankly, most states probably cannot meet this challenge within existing resources.

Although Texas can be characterized as having a restrictive Medicaid program, based on our income eligibility and limitations on optional services, I am pleased to say we do cover prescription drugs. At one point during our recent budget negotiations, it was suggested we might eliminate drug coverage since it is an optional service as a way to partially reduce our shortfall. Recognizing the significant health consequences and potential long-term cost implications, we chose to raise state revenue instead.

I want to focus my remarks today on the adverse effect I believe some of the proposals you are considering could have on the 1.2 million Medicaid recipients in Texas. As you know, a substantial number of the recipients are children. Another large segment is comprised of the sickest and poorest of our elderly population. The recipients also include pregnant women and persons with disabilities of all ages. By virtue of being eligible for Medicaid, these individuals are vulnerable and dependent on the state and Federal Government to some extent for their well-being.

Of greatest concern to me are the provisions which would require the cheapest possible prescription drug to be dispensed to Medicaid patients. As the author of the generic drug legislation in Texas, I obviously am in favor of offering less expensive, chemically-identical drugs in lieu of a name-brand product to achieve cost savings while maintaining quality. But, I think it is critically important to stress the difference between "generic" drug products and the "therapeutic substitutes" which would be required under these proposals.

As I understand it, therapeutic substitutes are seldom, if ever, chemically-identical. They will hot necessarily have the same effect on all people, and therefore may not achieve the desired outcome when taken by different individuals. A particular drug known to work very well on the majority can actually cause disastrous side effects and complications for other individuals.

The theory of "one illness, one drug" advanced in the S. 2065 and the OMB budget proposal overlooks the distinct differences among individual patients.

I am told there are even some highly successful medications which have been developed specifically for certain ethnic groups. Under a "preferred drug" policy, the decision about whether these drugs would continue to be available to Medicaid recipients would be based solely on one factor: cost. As a public policymaker, I could not endorse any proposal which might have the unintended outcome of denying access to the most effective drug in a therapeutic category.

I also have learned over the years that there are some decisions we must leave to our health care professionals. And in the case of prescribing medicine, this means the physician. Only they know their individual patients' unique medical conditions, their body chemistry, their tolerances or intolerances of certain prescriptive medicines. I believe there are ways to contain costs without tying the hands of those who are most knowledgeable and skilled in diagnosing and treating health problems.

The ultimate goal being advanced by the Pryor legislation and the office on Management and Budget [OMB) is to reduce expenditures for the prescription drug program. While we all agree this is a worthy goal, there is widespread disagreement about whether any real savings would be achieved under either of the proposals.

Several nationally-recognized medical authorities and well-respected research institutions have cautioned that restrictive drug formularies actually cause cost-shifting to other more expensive Medicaid services by increasing physician visits, testing procedures, and even hospital admissions. At least one of the university-based studies I have seen indicated the "preferred drug" concept can add as much as 15% to overall Medicaid program costs.

This kind of data frightens those of us in Texas whose basic health care component of the Medicaid program is currently costing around $3 billion. Any increase, particularly one the size of 15% or $450 million, would further complicate an already fragile and serious financial situation in our state.

I am submitting with the written statement a four-page memorandum from the Texas Department of Human Services which identifies other potential cost implications for our vendor drug program. without going into any detail, the agency estimates the cost of switching from a cost-based system to a charge-based system would add another $10 to $12 million in costs each year. Another $2.5 million annually would be necessary to comply with the expanded audit requirements for a charge-based reimbursement system.

In some respects, we feel the "substantial price reduction" provisions will reward those states which have made no effort to implement federally-recommended cost containment strategies and will penalize those who have demonstrated success in establishing efficient reimbursement systems by working in cooperation with Federal officials.

Our vendor drug reimbursement system is based on the estimated acquisition cost (EAC) drug pricing policy rather than the average wholesale price (AWP) still in use in a few remaining states. As an example, a state using the AWP might be paying $10 today for a particular drug product. To comply with these proposals under consideration today, this state would have to negotiate an $8.50 price. For comparison, using the EAC system, the current reimbursement would already be at $8.70 since the mandated payment is set close to the pharmacist's actual cost. Although it would appear Texas need only achieve another $.20 reduction to be on the same paying status with the other state, in fact, we would have to negotiate a rate of $7.40 in order to be in compliance. I hope this helps illustrate why we believe that states which are already using cost-efficient reimbursement systems could be penalized.

Because prescription drug costs comprise only around 6.5% of all Medicaid expenditures, the opportunity for savings can be relatively small in comparison to other areas of the program. The savings also can be more difficult to accomplish because any major structural or policy changes can cause human suffering and can drive up overall Medicaid costs for the state and Federal governments. For these reasons, I hope we will fully explore all of the alternatives available for containing costs.

At the annual Southern Legislative Conference (SLC) in July in Asheville, North Carolina, we adopted a resolution calling far immediate dialogue on prescription drug costs among state Medicaid administrators, pharmacists, pharmaceutical manufacturers, physicians, consumers, legislative leaders and other interested parties. The SLC initiative will include a 15-state evaluation of drug costs, and I have agreed to spearhead this effort in Texas. Our Health and Human Services Committee will be holding public hearings during the next few months as a part of the evaluation.

Clearly, we are equally concerned about spiralling costs at the state level. However, I would respectfully ask you to delay any further Federal mandates until we can complete this process and share our findings with you. We don't want to see Medicaid patients suffer, and we certainly don't want states which have efficient programs in place to be penalized. I am confident we can develop appropriate, cooperative cost-containment measures which will maintain access to quality prescription drug services for Medicaid recipients.

Mr. Chairman, I believe it is imperative to preserve a workable federal/state relationship that will deliver appropriate care and medications to the individual patients in a safe and cost-effective system.

MEMORANDUM

TEXAS DEPARTMENT OF HUMAN SERVICES

SUBJECT: Senate Bill 2605, Pharmaceutical Access and Prudent Purchasing Act of 1990

TO:
Al Giles
Director
Government Relations
State Office, 181-W

FROM:
Donald L. Kelley, M.D.
Deputy Commissioner
Contracted Client Services
State Office, 600-W

DATE: June 1, 1990

The changes made to Senator Pryor's pharmaceutical access and Prudent Purchasing Act as a result of earlier comments on S2605 have clarified the intent of the bill and greatly improved the definition section. A number of problems remain, however, that would adversely affect Texas and other states that have previously adopted responsible cost containment strategies in their Medicaid pharmacy programs.

Charge - Based Reimbursement (1927 (a)-(i))

Despite Senator Pryor's staff attempts to minimize the inflationary nature of this type system with costly and cumbersome audits, the basic inflationary tendency of charge - based systems has not been addressed. Such systems are not inflationary because providers misrepresent their customary charges, but because customary charges bear little relationship to the cost of doing business. Cost-relatedness is a long standing principal of Medicaid reimbursement; and recent state cost-containment measures in Medicaid pharmacy programs, far from being the "short-sighted reimbursement cutbacks to pharmacists" described by the Senator, have been legitimate attempts to pay pharmacists on the basis of their true costs plus a reasonable profit factor. To cite just one example of how charge-based reimbursement can differ from cost-based reimbursement, recent billings from one large chain provider indicate Usual and Customary charges for Diazepam at $21.50 for a one month supply. While this is a considerable savings over the brand name, Valium, the cost plus fee currently paid by Texas Medicaid for this product is less than six dollars! Clearly, reimbursement of the pharmacy's customary charge, even at the 90th percentile, would represent a tremendous overpayment of public funds. In Texas, the system of charge-based reimbursement mandated by S2605 would result in a 6% ($10 - $12 million per year) total loss to the program since current reimbursement averages 84% of reported Usual and Customary charges. It would also cost $2.5 million per year increase audit efforts for customary charge based to reimbursement.

Additionally, the proposed drug rebate system would push future customary charges, which currently increase at a rate of over 9% a year, higher as drug manufacturers "cost shift" the losses from Medicaid to the private paying customer. State Medicaid programs, unable even to consider other contractors' prices in determining customary charges, will end up continuing to pay for the rising cost of prescription drugs to the private sector. Medicaid programs, unable to participate like other contractors in negotiations with pharmacists, will be forced to pay ever increasing customary charges over which they have no control. It appears that S2605 will recreate, at the total program reimbursement level, the same problem its drafters are seeking to solve at the drug product reimbursement level. This problem is largely caused by a lack of knowledge of the costs involved in producing pharmaceuticals. Without the ability to relate reimbursement to cost, Medicaid programs and recipients would be totally at the mercy of providers of service.

Texas' highly successful system of reimbursement to pharmacies, which has been developed over the past five years, evolved in a climate of state/federal partnership and program flexibility. Our system has resulted in a broad, stable provider population and excellent access to services. There seems to be little logic in removing all state flexibility in pharmacy reimbursement, which will negate established program savings. Savings attributable to drug rebate programs should be in addition to current program savings rather than instead of them. States should retain the flexibility to work with all the participants in the prescription market place to capture all potential savings for Medicaid programs.

"Preferred" Drugs (3 (g))

Senator Pryor's comments on his proposal indicate he does not favor creating restrictive formularies. Indeed, in some states where whole therapeutic categories have been eliminated as a cost containment measure, S2605 would restore some drugs to formularies. The problem with S2605 is that, since across the-board rebates in the amount specified by the bill are unlikely, current open and broad formularies will have to be restricted in order to generate any savings. Of course, there is still no guarantee that a system of preferred drugs would save money, since extensive overrides by physicians would negate the majority of such savings.

Substantial Price Reduction (3(m))

This section is apparently intended to mean that states must achieve approximately 15% savings in drug product cost over what they currently pay for drug products or would pay if their current system continued. This definition of "substantial price reduction" places states that have implemented estimated acquisition cost (EAC) drug pricing policies at a substantial disadvantage over the minority of states that have continued to pay average wholesale price (AWP) for drugs. As an example, on a $10 AWP drug product, a state such as Arkansas need only negotiate an $8.50 real drug product cost (after rebate) to comply with the law. In Texas, however, where EAC policies mandate payment close to the pharmacists actual cost of approximately $8.70 for the same drug, the state would have to negotiate a real price, after rebate, of $7.40 in order to be in compliance. In other words, this part of S2605 advantages states that have made no effort to effect federally recommended cost containment strategies over those that have been successful in that respect.

Additionally, this definition of "Substantial Price Reduction" as 15% off the current system seems rather arbitrary and certainly would limit states in their attempts to negotiate rebates with drug manufacturers.

Drug Utilization Review and Electronic Billing

Texas is currently exploring these two areas and is supportive of S2605 in its encouragement of such systems for Medicaid programs.

Summary

S2605 can best be described as a reimbursement system that would "rob Peter to overpay Paul." The real beneficiary of this legislation would be the pharmacists, not Medicaid programs that would be forbidden from exercising flexibility in developing cost based pharmacy reimbursement systems; nor Medicaid recipients, who would eventually lose services as charge-based reimbursement systems escalated the cost of Medicaid pharmacy programs. Texas' experience suggests that fair, cost-based reimbursement systems to pharmacies result in stable provider populations, excellent access to services and no diminishment in the quality of pharmacy practice. We are in favor of any additional measures that can be taken to control rising costs in Medicaid drug programs, but we believe that a system that controls charges by gaining adequate evidence of what it really costs to develop, manufacture, and market prescription drugs and then relates payments to costs, would better serve the public than one that merely takes advantage of the mysterious differential pricing systems already in place.

If, however, Medicaid rebates are to be implemented, they should be used to gain additional program saving and control potential future costs. By retaining currently available program savings and adding to them, the real beneficiaries will be the Medicaid program and the recipients it serves.

Donald L. Kelley, M.D.

DLK:srs

PREPARED STATEMENT OF JAMES CLOYD

Mr. Chairman, Senator Chafee and other Members of the Subcommittee: Good morning. My name is James Cloyd and I am here today on behalf of the Epilepsy Foundation of America (EFA). The Foundation appreciates this opportunity to discuss the various proposals which have been offered to restructure the Medicaid Prescription Drug Program. The Epilepsy Foundation of America, founded in 1968, is the sole national consumer organization representing the interests of the more than two-and-a-half million Americans with epilepsy.

I am here today for both professional and personal reasons. My father had epilepsy so I am personally aware of many of the problems associated with this complex medical disorder.

My professional qualifications include a B.S. and Doctoral degree in Pharmacy and employment as Associate Professor of Pharmacy within the College of Pharmacy at the University of Minnesota. I am also Head of the Department of Pharmacy Practice.

I also serve on the Professional Advisory Board of the Epilepsy Foundation of America. As a voluntary health agency, EFA relies upon its 50 member Professional Advisory Board for advice on technical medical issues including such matters as drug development, efficacy and safety. EFA invited me to serve on their Professional Advisory Board because of my position as a Clinical Pharmacist at the Comprehensive Epilepsy Program at the University of Minnesota. My job is to assist my medical colleagues in providing safe, effective and economical drug therapy for patients with epilepsy.

Epilepsy is really a misnomer. The more appropriate term is the epilepsies since there are many different seizure classifications. Some forms of epilepsy are convulsive while others are not. The epilepsies are very complex disorders to diagnose and treat. Finding the appropriate drug or combination of drugs is often an extremely lengthy and frustrating experience for an individual with epilepsy. Technological advances using imaging devices and blood level monitoring have greatly contributed to the medical community's ability to more effectively control seizures using the limited number of available antiepileptic drugs.

Just as the effects of epilepsy are very individualistic, so are the experiences of individuals, who have the same type of epilepsy, when prescribed the same dose of an antiepileptic drug due to physiologic and metabolic factors.

One person, for instance, with complex partial seizures may be completely controlled on the same dose of a specific medication without significant side effects while another individual might experience serious side effects. Yet a third person might not achieve any seizure control with the same drug.

The Foundation has followed with great interest and much concern the various proposals which have been advanced to restructure Medicaid's prescription drug program including: Senator Pryor's initial bill (S. 2605); the Office on Management and Budget (OMB) initiative; the rebate programs proffered by drug manufacturers particularly Merck; and Senator Pryor's new legislation, S. 3029.

EFA has particular interest because (1) drug therapy is the mainstay of treatment for people with epilepsy; (2) optimum drug therapy assists approximately 80 percent of all people with epilepsy achieve seizure control and quality of life; and (3) antiepileptic drugs unlike most other drug categories possess a relatively narrow range in which seizure control is achieved with minimum toxicity. The six drugs primarily used in the treatment of epilepsy are: (generic/brand): carbamazepine (Tegretol); ethosuximide (Zarontin); phenobarbitol; phenytoin (Dilantin); primidone (Mysolin); and valproate (Depakene/Depakote).

Each of the proposals before this Committee seek to reduce Federal Medicaid expenditures for prescription drugs—an amount which totalled $3.9 billion during fiscal 1989. Not only does EFA applaud this goal, we would be happy to share at another hearing alternatives on how to use these savings to expand Medicaid coverage to better meet the needs of Americans with chronic health conditions. The difficulty arises with the means to this laudable goal.

The Foundation remains opposed to the OMB proposal because therapeutic substitution would have seriously adverse consequences to many people with epilepsy. While the Foundation has not taken a final position on S. 2605, we believe it is seriously flawed and would require substantial amendments to protect the health care needs of people with epilepsy. While S. 3029 is a major step in the right direction, several provisions need revision before EFA is in a position to support its enactment. The Foundation offers the following specific comments regarding the various pending proposals.

I. OMB PROPOSAL: THERAPEUTIC SUBSTITUTION

The most flawed proposal before the Committee is the OMB initiative permitting therapeutic substitution. EFA, along with several professional associations, has long been opposed to the substitution of any prescribed antiepileptic drug (whether generic or brand) without the prior approval of the patient and the physician.

There are important differences between drugs in the same therapeutic class and substituting one drug for another may well result in people with epilepsy either experiencing seizure(s) or toxic side effects. Physicians, after careful medical evaluation of their patients, know best what their patients need. It is unacceptable for a bureaucratically established process to second guess what is appropriate treatment for a particular individual with epilepsy as the OMB proposal would permit. Solutions such as the OMB proposal which threaten the health of Americans with chronic health conditions like epilepsy must be rejected outright.

II. THE PHARMACEUTICAL ACCESS AND PRUDENT PURCHASING ACT (S. 2605)

Therapeutic Alternates and Drug use Classes

S. 2605, the Pharmaceutical Access and Prudent Purchasing Act, takes a slightly different approach. The National Pharmacy and Therapeutics (NP&T) Committee, envisioned by S. 2605, would group all outpatient drugs into one or more drug use classes based upon medical indications. "Drug use class" is defined as "a group of covered outpatient drugs that has the same intended use."

The NP&T Committee would determine which drugs within each drug use class are therapeutic alternates. It defines therapeutic alternates as two or more drugs that contain different therapeutic moieties but are of the same pharmacological or therapeutic; class and can be expected to have a similar therapeutic effect when administered to patients in a therapeutically equivalent dosage. States would then determine a "preferred drug" among therapeutic alternatives based, in large measure, upon which drug is available at lowest cost.

This approach is seriously flawed as it relates to drugs used for conditions such as epilepsy. Being therapeutic alternates does not ensure that two or more drug products mare either as effective or as safe in differing individuals. As previously mentioned, people with epilepsy have widely varying reactions to specific artiepileptic drugs, even though the drugs are equally appropriate for the indication (specific seizure type). People have differing metabolisms and family histories. They may have other medical conditions which affect drug absorption or tolerance. Many people take more than one antiepileptic drug or drugs for other medical conditions. Finally some people are allergic or sensitive to specific classes of drugs. Finding the right drug therapy for individuals is difficult at best. Physicians must be permitted maximum flexibility to prescribe what is best for their patients. For instance, 13 drugs including carbamazepine, phenobarbitol, phenytoin and sodium valproate are used to treat generalized tonic-clonic (grand mal) seizures. Phenobarbitol has markedly different side effects in some patients than does phenytoin or carbamazepine and sodium valproate, yet phenobarbitol is significantly lower in price than any other drug within this indication.

The term "drug use class" should be more narrowly defined and "indication" should be defined. One "nationally recognized" classification system is the U.S. Pharmacopoeia. The U.S.P., for instance, identifies 8 separate epilepsy-related indications as follows: (1) Absence, (2) akinetic, (3) complex partial, (4) epilepsy-mixed seizure patterns, (5) myoclonic, (6) simple partial, (7) tonic clonic and (8) status epilepticus. S. 2605 does not adequately address whether antiepileptic drugs would be placed into one broad classification (antiepileptic drugs) or several based on each specific seizure type. The definition hinges upon how the phrase "drugs that has the same intended use" would be interpreted by the NP&T Committee. This is too important to leave legislatively undetermined.

Physician Override

S. 2605, would only reimburse pharmacists for disbursing "preferred drugs" *unless* the physician has issued a restrictive prescription for a non-preferred drug. The physician must write the words (brand name) medically necessary on the prescription or used those words when communicating the prescription by phone.

If the physician fails to specify "brand medically necessary" the pharmacist must clarify with the physician whether a preferred drug in the same drug use class is acceptable for the patient or that the prescription is intended to be restricted.

EFA fears that this process may prove burdensome to all concerned—the pharmacist. the physician and, most important of all, the patient. Most troubling is the provision that limits the pharmacist from providing more than a 72 hour supply of the non-preferred drug when he or she has been unable to communicate with the prescribing physician.

This places a terrible burden and inconvenience on the Medicaid recipient. Not everyone lives within walking distance of a pharmacy. Many people with epilepsy are unable to drive. What if they are unable to get back to the pharmacy within 72 hours? If this individual has a seizure and is taken to an emergency room or visits a physician, whatever savings will be lost. In addition, the person with epilepsy having a breakthrough seizure risks serious injury and the potential of major economic and personal loss. EFA recommends issuing at least a two week supply of medications when the pharmacists is unable to reach the physician.

The physician override provisions of S. 2605 at least recognize the importance of permitting treatment decisions to be determined by the physician—not some unspecified state agency clerk as provided for in Senator Pryor's new bill. S. 3029 must permit physicians to control treatment decisions.

Pharmacy and Therapeutics Committee

The NP&T Committee, envisioned by S. 2605, would be comprised of professionals with recognized knowledge of appropriate drug utilization, relative safety and efficacy including an "individual with expertise in psychiatric or neurological problems." The Foundation's experience with "expert" panels established by national medical groups leads us to question whether the interests of people with epilepsy would be adequately represented by having just one expert in the neurosciences given the fact that there are over 600 neurological conditions.

The bill also requires the P&T Committee to solicit advise from advisory panels. The bill should specify the establishment of a panel which would provide advice on which medical conditions, such as epilepsy, should be exempt from the provisions of the bill due to the severity of the condition; the pharmacologic difficulty of manufacturing drug products; and metabolic problems associated with drug treatment regimes. The bill currently provides for an advisory panel dedicated to problems and perceptions of consumers. Another panel should be created to include representatives of patient advocacy groups.

III. MEDICAID ANTI-DISCRIMINATORY DRUG PRICE AND PATIENT BENEFIT RESTORATION ACT

Senator Pryor's new bill is based, in part, on the initiative introduced earlier this year by Merck. This legislation, S. 3029, requires each manufacturer wishing to participate in the Medicaid program to provide Medicaid the same substantial discounts or "best prices" provided other purchasers of its medications.

While S. 3029 promises to achieve substantial savings without many of the administrative costs associated with S. 2605, it has several problems which must be redressed if this proposal were to be enacted. These problems related primarily to the accessibility of medically necessary prescription drugs.

Drug Accessibility

S. 3029 states that all drugs from a participating manufacturer are eligible for reimbursement under Medicaid. While this provision is a notable improvement over existing law, S. 3029 takes a step backwards when, another section, grants states the authority to establish a prior authorization process. This process would, in effect, be a state formulary. EFA is opposed to this provision as it stands. All drugs of participating companies should be available to patients. Prior approval should only be required for drugs marketed by companies not participating in the Rebate Program or for a limited number of extraordinarily high price drug products. If it is the intent to permit limited access to a few high a price drugs, then this section should be redrafted accordingly otherwise we urge elimination of this authority. To do otherwise ensures inequitable medical care, uncertainty and burdensome administrative provisions.

Prior Authorization

While we urge elimination of this provision for companies participating in the Rebate Program, at a minimum, we believe it must be amended to: (1) require states to establish an open process including a public hearing and an appeals process when deciding which drugs require prior authorization; (2) establish a timely process permitting a physician to appeal any denial issued under the prior authorization program; (3) permit the physician to prescribe a limited supply of a drug when his or her initial request is denied, and (4) provide additional language regarding what constitutes an acceptable rational for denial.

Drug Formularies

The Foundation is strongly opposed to the establishment of highly restricted formularies which are far removed from daily clinical practice. Restricted formularies currently exist in selective Medicaid programs and in institutional settings. There are differences between these types of formularies. The latter which are found in hospitals are developed and constantly reviewed by medical practitioners concerned with the medical needs of specific patients. These formularies are carefully developed to ensure the availability of quality medications at reasonable costs. State Medicaid formularies, on the other hand, are far removed from clinical practice and patient considerations. Their purpose is primarily to generate savings by narrowing the availability of medications. This method of determining reimbursable drugs often serves to deny or seriously limit access to newer and often more effective or safer medications.

Several studies from selected states where formularies have been in place, have shown that costs will rise rather than fall. These studies indicate that restricted formularies increase total Medicaid costs between 4 to 15 percent because those denied appropriate drug therapies may require more expensive alternative' treatment such as additional physician services, hospitalization or surgery.

While EFA has not independently reviewed these studies, its conclusions seem consistent with the experience many individuals have in securing and maintaining effective seizure control.

Narrow Therapeutic Range Drugs and Generics

S. 3029, as drafted, prohibits reimbursement after April 1, 1991 for innovator (brand) multiple-source drugs. This provision must be amended to permit physicians to prescribe brand formulations. *All generic drugs are not therapeutically equivalent to the innovator product under existing standards.* The FDA has identified 24 narrow therapeutic range drugs (see attachment) defined as drugs where "quality specifications are generally considered to be critical" used to treat disorders such as epilepsy, high blood pressure and asthma. These drugs, together with "hard-to-copy" products, present a special problem which this legislation must be amended to address.

The American Academy of Neurology issued a statement earlier this year on the problems associated with generic substitution of antiepileptic drugs (see attachment). Every formulation of a particular drug (whether brand or generic) a differs from each other. Each differ in the rate and extent of absorption. These difference can and will cause problems with patients. The use of narrow therapeutic range generics present a significant problem which must not be overlooked or classified as mere "generic drug bashing." The FDA, together with the U.S.P. have recently begun tightening the manufacturing standards for two major antiepileptic drugs. This is a long and complicated process. EFA strongly urges that narrow therapeutic range innovator multiple source drugs be specifically exempted from this proposed exclusion provision.

The costs associated with switching a patient from one formulation of a drug (whether brand or generic) to another formulation (i.e., blood tests, loss of seizure control, adverse side effects) are likely to be higher than any savings achieved through the mandated use of generics.

A related problem stems from the lack of markings on generic products which would permit consumers to easily identify the manufacturer of the drug. Such markings must be required before this provision of S. 3029 receive approval.

Manufacturer markings are necessary, particularly for narrow therapeutic range drugs, to permit consumers wishing to use a generic product to be assured that they will remain on the same generic formulation when the prescription is refilled. Otherwise they risk experiencing a therapeutic failure or toxicity.

Base Price Indexing

S. 3029 would establish as the "best" price the lower of either the market price offered each calendar quarter or the lowest price offered as of September 1, 1990. This amount would be indexed to the consumer price index.

Senator Pryor has pointed out that prescription drug prices rose 123 percent over the past decade (1980–89) compared to 50 percent for the overall CPI. Yet the medical care component of the CPI increased by 99 percent during this time period.

EFA is not in a position to comment on what constitutes a reasonable rebate. We do question whether using the consumer price index (CPI) is reasonable. It would seem more appropriate to use either the medical research inflator or the medical care component of the overall CPI.

"Me Too" Drugs

Much has been said about so-called "Me-too" drugs. We understand the desire to limit the practice of developing new drug products which are very similar to existing products and which do not significantly add to available drug therapies. EFA thinks it is important to clarify that some new drug products, although similar to existing products, offer significant clinical benefits to patients. Individuals taking antiepileptic drugs, particularly the older and, it is important to point out, less expensive drugs such as phenobarbitol often experience serious side-effects. Several new antiepileptic drugs currently undergoing clinical trials show potential as being as effective as existing drugs while having fewer side effects. Others, which are chemically similar to existing products, offer longer half-lives permitting extended release of the drug allowing individuals to take fewer doses daily.

The FDA rating given these new drugs, if eventually approved, would not reflect the contribution these products will make to improving the lives of individuals taking the older, more toxic drugs. If the FDA ratings are to be used to evaluate the contribution of new drugs, then they must evaluate improved tolerance.

Drug Utilization Review

S. 3029 establishes a mechanism to improve consumer understanding of the proper uses of their medications and the problems associated with taking multiple drugs. These provisions are commendable since they seek to maximize the benefits which are derived from drug therapy while minimizing the problems. This legislation would strengthen the important role currently performed by pharmacists.

CONCLUSION

Not all uses of prescription drugs are equivalent. Many drugs are used temporarily to treat an illness. Others are used to reduce pain. Some drugs mean the difference between life or death. Other drugs mean the difference between an individual leading a relatively unencumbered life or being seriously disabled. This is certainly the case with antiepileptic medications.

These various proposals raise many serious questions. While the goal is to reduce Medicaid expenditures, new bureaucracies and administrative procedures must be avoided. Limiting access to certain drugs may also increase other expenditure categories such as physician visits or hospitalizations not to mention affect the quality of life for people with chronic health conditions such as epilepsy.

If the Finance Committee were to pursue an approach similar to S. 2605 or S. 3029, we strongly recommend adopting provisions which recognize the problems associated with narrow therapeutic range drugs used to treat medical conditions such as epilepsy where it is essential to maintain a stable drug level within the blood stream to prevent the occurrence of life-threatening situations such as status epilepticus or prolonged seizures.

The Foundation appreciates the difficulty in crafting a new legislative vehicle affecting health care. EFA believes it is essential to build protections into any legislation in order to ensure individuals with epilepsy who are Medicaid beneficiaries receive appropriate medical treatment.

The Foundation strongly urges that any legislation reported out of this Committee must ensure: (1) access to all drugs determined "medically necessary" by the individual's physician including all narrow therapeutic range innovator drugs until tighter therapeutic ranges are adopted by the Food and Drug Administration and the U.S. Pharmacopeia; (2) reasonable prior approval procedures including a timely appeal process; (3) achievement of cost-savings without burdensome new administrative processes; (4) adequate incentives to ensure the development of improved drug products; and (5) consumers receive the types of information which assist them to make better decisions about their own health.

The Foundation appreciates this opportunity to appear before you today.

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: November 13, 1989

FROM: Acting Director, Office of Generic Drugs

SUBJECT: Narrow Therapeutic Range Drugs

TO: Dr. Peck
Mr. Michels

The Commissioner has expressed concern about the possibility that drugs with narrow therapeutic range were not targeted in the list of top 30 generic drugs screened through the field sample acquisition and assay program. As an initial response, the areas of anti-convulsant drug products and anti-asthmatic drug products were identified. These were felt to be drug groups where modest deviations from bioequivalence potentially could result in adverse clinical outcomes, either adverse reactions or therapeutic failure. Comprehensive lists of anti-asthma and anti-convulsant drugs include more than 60 products. After medical review of this list, it was obvious that while a substantial number of these products, in fact, did have a relatively narrow therapeutic range, there were also products included for which the therapeutic index was quite broad. In addition, there are products in other therapeutic areas which also have a narrow therapeutic range. Therefore, Dr. Dighe was asked to develop a list of multi-source drugs that would not receive bioequivalence waivers, for which there was information on the therapeutic range in the literature, and for which the therapeutic range was relatively narrow. This list was then circulated to the Directors and Division Directors in the Offices of Drug Evaluation I and II who have provided comment and input. This list was reviewed by Dr. Peck and is attached. Only drugs that have approved ANDA's and are for oral or inhalation dosing are included. There are insufficient data to establish internal ranking for the drugs that are on this list. While we may well update and refine this list, given the understanding that it is not considered definitive, it nonetheless seems like a reasonable starting place for this purpose. Please note that a parallel evaluation is being developed for products that, based on the Center for Drug Evaluation's understanding of the problems involved in manufacturing, are likely to be hard to manufacture by a new company.

Bruce Burlington
D. Bruce Burlington, M.D.

Attachment

Drugs with Narrow Therapeutic Range of Low Therapeutic Index

Generic Name

Aminophylline Tabs

Carbamazepine Tabs

Clindamycin Caps

Clonidine Tabs

Dyphylline Tabs

Disopyramide Caps

Ethynil Estradiol 30 & 35 mcg (in combination oral contraceptive tabs)

Guanethidine Tabs

Isoethrane MDI

Isoproterenol MDI

Lithium Carbonate Caps & Tabs

Metaproternol Tabs

Minioxidil Tabs

Oxytriphylline Tabs delayed release

Phenytoin Caps - extended

Prazocin Caps

Primidone Tabs

Procainamide hydrochloride Caps & SR Tabs

Quinidine Sulfate & Gluconate

Theophylline Tabs & Controlled Release Tabs

Valproic - acid

Valproate - sodium

Warfarin Sodium Tabs

AMERICAN ACADEMY OF NEUROLOGY

Position Statement

TECHNOLOGY ASSESSMENT: GENERIC SUBSTITUTION FOR ANTIEPILEPTIC MEDICATION

A Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology

Generic substitution for brand name antiepileptic medication now occurs frequently in the U.S. Concern exists that some generic antiepileptic medications do not provide satisfactory therapeutic equivalence to the brand name product for which they are substituted, and that generic antiepileptic drugs also may not adequately substitute for each other.[1-3] These concerns have been voiced most often regarding the drugs phenytoin and carbamazepine. The principal advantage of generic substitutions is cost containment. This economic goal must be balanced by quality assurance concerns. Any assessment of that balance must include a knowledgeable interpretation of the relevant principles of pharmacology and clinical neurology, as well as the relevant social and economic issues.

Current FDA guidelines are based on the assumption that bioavailability can vary safely by 20%.[1] There is no scientific evidence that this, or any other range of variability, can be tolerated safely by patients with epilepsy.

Three pharmacologic risk factors have been identified that are associated with difficulty in creating a new drug formulation: low water solubility, a narrow therapeutic range and nonlinear pharmacokinetics. Phenytoin possesses all three of these risk factors, and carbamazepine possesses the first two. Despite such pharmacological complexities current regulations require only a very limited testing for generic phenytoin and carbamazepine, the same as for other generic products that do not have a narrow therapeutic range. The generic/brand name bioavailability ratio measured in individual subjects has varied from 74% to 142% in reports to the FDA.[1,4] Exacerbation of this intraindividual nonequivalence may occur due to various confounding factors, such as the drug interactions that occur with concurrent medications. Other potential confounding problems include: (1) variations in time to maximum blood level after each dose; (2) individual sensitivity to the different binding or coloring agents;[5] or (3) variability in shelf life.

Generic medications may also create confusion that can be annoying and sometimes dangerous for persons with epilepsy. The physician and the patient have difficulty in determining the cause of rising or falling blood levels and episodes of breakthrough seizures and drug toxicity, under the best of circumstances. Some patients require delicately balanced therapy. These problems are exacerbated by generic substitution when neither patients nor physicians are kept informed about which manufacturer's generic formulation is actually dispensed at a particular time. Many generic tablets and capsules are not identified by any easily identified marks or characteristics, in contrast to brand name tablets and capsules which are almost always distinctly labeled or identified. These nonlabeled pills can be difficult to identify, compromising medical care, especially in emergency room settings.

This statement is provided as a service of the American Academy of Neurology. It is based on current scientific and clinical information, and does not represent endorsement by the AAN of particular diagnostic and therapeutic procedures or treatment.

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The effects of therapeutic nonequivalence can be dramatic in the case of antiepileptic medication, and these can far outweigh the economic advantages of generic substitution. Breakthrough seizures in a previously well controlled patient with epilepsy can be catastrophic. Seizures while driving can severely injure or kill innocent bystanders. Even if the patient were not injured in breakthrough seizures, the loss of driving privileges and other social ramifications can cause severe hardship. Loss of work time can occur both for breakthrough seizures and for drug toxicity. Seizures and toxicity also lead to increased physician visits, increased ordering of blood level tests and additional loss of work hours for each of these. The increased visits and blood level tests will happen for many patients even without clinically apparent toxicity or breakthrough seizures, simply as a means of attempting to prevent such problems. These hidden costs represent a serious flaw in the economic incentive for generic substitution, which can result in additional costs that far outweigh any small cost savings accruing from use of generic medications. In particular, a $10-100 annual cost savings by using generics would be cancelled out many times over by just a few extra physician visits and blood level tests during that year. Although the patient will bear the risk for seizures, he or she will gain little in cost savings even when no new expenses are incurred.

Relatively few states require that wholesale cost savings be passed along to patients.[6] Retail store price surveys have even shown that price differences between different stores can be greater than a specific store's price differential between brand and generic formulations of a drug. In a given town, there are examples of stores charging more for the generic than a competitor charges for the analogous brand name drug.[7-8] For an individual patient, shopping around for the lowest price on the brand name medication can be a bigger cost savings than switching to generic.

Pharmacists are being asked to make generic substitutions, and yet they are not in a professional position to decide whether an antiepileptic drug generic substitution is reasonably safe for an individual patient. HMOs and hospital formularies, third party carriers, Medicaid and Medicare have implemented mandatory substitution policies without sufficient discretion regarding individual patient circumstances. Such substitutions are covert since they are done without the knowledge or consent of either the patient or the physician and often without even the notification of either. This is a substantial confounding factor for patient care, which may even prevent identification of the generic substitution as the culprit causing clinical problems. The lack of informed consent also creates concern about a liability problem: Lawsuits regarding breakthrough seizures or disability from drug toxicity may well name physicians, especially in states where the pharmacists and drugstores have gained statutory protection from lawsuits resulting from generic substitution. Liability for damages resulting from generic substitution, without explicit physician approval, ought to be the responsibility of those who instituted the policies and statutes allowing such substitution. Regulatory bias favors substitution in many states by forbidding physician control of generic substitution through such simple means as placing a check in a preprinted box.

These many problems and the patient care difficulties from generic substitution have been obscured by the often repeated myth, "No patient has ever been harmed by a generic drug." There are well-known published reports of clinical nonequivalence with breakthrough seizures or increased seizure frequency upon generic substitution[9-12] or in toxicity upon dispensing a different formulation.[13] Published reports also document that generic antiepileptics do have different rates of absorption, bioavailability and blood levels.[14-17] Even changes in the formulation or administration of brand name antiepileptic medications have caused clinically significant effects.[18-20] Some outbreaks of clinical problems have resulted in recalls of generic antiepileptic medications.[21-22] These various clinical effects are unpredictable, and sometimes substitution results in significant change in blood levels[23] or clinical efficacy.[24] Generic drug manufacturers and the FDA have challenged some reports of nonequivalence as being too anecdotal.[25-27] Recognizing that the anecdotal nature of reports does not detract from their significance, many members of the AAN have provided us with examples of serious clinical problems that they attributed to generic substitution. For antiepileptic medications, the problems involve primarily phenytoin and carbamazepine. Some other antiepileptic drugs may or may not have generic substitution difficulty, because they possess few pharmacologic risk factors. Still other antiepileptic medications are quite well suited for substitution, e.g., among various generic formulations of phenobarbital.

Much of the disadvantage of generic substitution results from switching, often repeatedly, from one carbamazepine and phenytoin formulation to another. Other problems include mandated substitution policies without notice to patient or physician and quality control issues. All of these could potentially be overcome. At the present time, however, the obstacles are substantial, and it may require some time before policies, laws and habits can be changed sufficiently to allow a widespread effective generic substitution for phenytoin and carbamazepine. Under existing circumstances, the following is recommended:

(1) Generic substitution can only be approved if safety and efficacy are not compromised. Patient safety and drug efficacy may be unduly compromised by indiscriminate switching to, from or between generic drugs for patients taking phenytoin or carbamazepine.

(2) Physicians should avoid switching between formulations of antiepileptic medications except when medically necessary, particularly for carbamazepine or phenytoin. They also should monitor blood levels closely at the time of any known or suspected switch to a different formulation. Medication doses should be readjusted accordingly.

(3) Specific information about each antiepileptic generic drug should be made available to physicians, including area under the curve bioavailability, time to maximum serum concentration, dissolution rate and reported complications.

(4) Pharmacists should be required to inform patients and physicians when switching a patient between different formulations of antiepileptic medications, and each prescription bottle should be labeled sufficiently to identify the specific manufacturer of the product dispensed.

(5) Any organization that encourages or requires generic substitution of antiepileptic medication, including federal and state agencies, hospitals, health plans, third party carriers, Medicaid and Medicare should evaluate its position regarding this problem.

(6) More research is needed to assess the impact of generic drugs in patients with epilepsy as well as in other clinical situations where fluctuating drug levels can produce disastrous affects.

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This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurological problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

U.S. Government employees who participated in the development of this technology assessment did so in a private capacity. No official support or endorsement by the U.S. Department of Health and Human Services or the Veterans Administration is intended or should be inferred.

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Approved PC	05/04/90
Approved EB	05/05/90

PREPARED STATEMENT OF CONGRESSMAN JIM COOPER

Sometimes an idea comes along that is so simple, so powerful, and so compelling that people wonder why it hadn't been considered years before. Our colleague in the other body, Senator Pryor, has come up with such an idea, and my House colleague Ron Wyden and I introduced legislation last Wednesday in the House to implement that idea.

The idea is simple. When the U.S. Government is a large purchaser of something, it should be able to negotiate to get either the lowest possible price, or at least as good a price as other bulk purchasers are getting. The U.S. Government should be run more like a business, which almost always bargains to get the best possible deal. The converse of that is the Government should never blindly pay the highest possible prices, thus wasting precious taxpayer dollars, because it forgets to ask for a discount.

In many cases, the U.S. Government does get reduced rates. When the Federal Government purchases everything from automobiles to fountain pens, even renting hotel rooms, a substantial discount is available from the supplier.

I think most Americans would be shocked to learn that the U.S. Government, through the Medicaid program, is the top purchaser of prescription drugs in America and yet rarely even gets the discounts that smaller purchasers get. In fact, we taxpayers usually end up paying top dollar. In most cases, Government hasn't even tried to get lower prices. we've let the drug companies tell us how much they would like to be paid, and we have paid them with no questions asked.

The cost of this extravagance has been largely hidden, but it has been extraordinary. This legislated, unrecorded subsidy to the pharmaceutical industry has cost the nation's Medicaid program, and thus the nation's taxpayers and poor, hundreds of millions of dollars, according to both the Congressional Budget Off ice and the Office of Management and Budget. This vast amount of money has not reached the poor in America primarily because the U.S. Government did not get a better deal from U.S. drug companies.

This is not to say that the U.S. pharmaceutical industry is all bad. Far from it. It leads the world in innovation and quality. Countless lives have been saved and improved as a result of the industry's research and product development. Being the world leader is not cheap. It takes money and lots of it. But the drug companies have found one way of getting lots of money from the Federal government without the need for an appropriation or even an explanation. By simply refusing to bargain with the Federal government, they have created a secret subsidy for themselves that is unfair to the taxpayers and poor of America.

The U.S. pharmaceutical industry gives discounts to the vast majority of hospitals in America because they are smart enough to demand them. The industry also gives lower prices to the Department of Veterans Affairs hospitals and to health maintenance organizations. Why not to their biggest customer, the U.S. Government's Medicaid program?

Some states have caught on to this game and have begun the bargaining process. But they have often been forced to resort to formularies, restrictive lists of drugs that Medicaid patients may be prescribed, in order to gain a bargaining advantage with the drug companies.

The Federal Government has the power and the responsibility to make sure that every state, every taxpayer, and every poor person, is protected from wasteful spending in the Medicaid program. The Pryor-Wyden-Cooper bill, which we introduced last Wednesday, achieves these savings without harming the legitimate interests of either poor citizens or drug companies. This bill should be distinguished from an earlier bill, S. 2605, which Senator Pryor introduced on the same subject but with a significantly different set of solutions.

This bill we are introducing today assures access to the best prescription drugs on the market for our nation's poor. No one need fear the creation of a system of second-class drugs for our nation's poor. In fact, the estimated budget savings of $2.5 billion over five years that this bill will produce should allow the Medicaid program to reach out to many more people in order to serve them better.

Major companies in the U.S. pharmaceutical industry itself have shown that they can live quite well when they give discounts to their largest customer. Several leading drug manufacturers have offered voluntarily to treat the U.S. Government as they do their other large customers, instead of discriminating against it. Unfortunately, these voluntary industry initiatives, while commendable, do not go far enough and lack adequate safeguards. To be sure, the Pharmaceutical Manufacturers Association is still against the legislation, as you would expect a trade association to be. But I feel that it is losing more and more of its members on the issue. These companies expect discounts from their suppliers; the Federal Government expects discounts from its suppliers.

The Leadership of the pharmaceutical industry will be tested by the manner in which it wages this fight. Will it sink to the lowest common denominator and fight to the last breath of the last company that wants to preserve this hidden and unfair subsidy? Or will it be thankful for the many years the U.S. Government has paid it top dollar, and argue for open, efficient subsidies that it is prepared to defend in public and on the merits?

To be honest with you, the first skirmishes have not been encouraging.

A very common tactic has been used: Discredit the first Pryor bill in the hopes that all subsequent legislation, such as the bill we introduced Wednesday, will either not be noticed or discredited.

Another tactic: Don't work with the Congress to improve the legislation and discourage those companies who are willing to; make Congress figure out everything on its own.

Efforts have even been made by the pharmaceutical industry to convince our nation's poor that they are better served with the current system, which has often denied patients access to health care, than it could be if we did not secretly funnel money to the pharmaceutical industry.

Efforts have also been made to hide the fact that so many of the new and expensive drugs being introduced today are so similar to existing drugs that they are little more than an excuse for a price increase. So much of our technological talent is being wasted on "me-too" drugs that cost a lot more and but don't cure a lot more.

I would hope that this is an issue that businessmen in the pharmaceutical industry would treat as businessmen. Don't discriminate against your biggest customer, even if it is the Federal Government. Don't treat Uncle Sam like Uncle Sucker. Why? Because we all lose as taxpayers and as a nation when we exploit our own Government.

I am not an enemy of the pharmaceutical industry. In fact, I have generally supported their initiatives. I am open to any argument they want to make for open, targeted subsidies to help it bring need drugs to market. I am an enemy of waste, and of secret subsidies at the taxpayers' expense. The pharmaceutical industry of America needs to treat our taxpayers with more respect and offer them, and the poor of America, at least the discounts that they offer to other groups.

I thank again my colleagues, David Pryor of Arkansas and Ron Wyden of Oregon, for joining me in this important legislation.

PREPARED STATEMENT OF NANCY W. DICKEY

Mr. Chairman and Members of the Subcommittee: My name is Nancy W. Dickey, M.D. I am a family physician in Richmond, Texas and a member of the AMA Board of Trustees. With me is Michael Zarski of the AMA Division of Legislative Activities.

The American Medical Association appreciates this opportunity to address proposals for payment of drugs under Medicaid.

Before discussing these proposals, let me tell you about the Association's interest in improving Medicaid coverage for those in need. The AMA has devoted much attention to this issue. We have studied and identified the severe inequities in the current Medicaid program and we have concluded that the program is in need of reform. The AMA proposals to modify Medicaid include:

1. The creation of basic national standards of uniform eligibility for all persons below poverty level income (adjusted by state per capita income factors);
2. The creation of basic national standards of uniform minimum adequate benefits;
3. The elimination of the existing categorical requirements; and
4. The creation of adequate payment levels to assure broad access to care.

We recognize that the costs of these reforms will be great. Indeed, merely to continue providing the current level of care to Medicaid beneficiaries without such improvement will require increased resources.

Under these circumstances, we must be comprehensive in our examination of the elements that contribute to the cost of health care for Medicaid beneficiaries. One element that the AMA and others have studied recently has been prescription drugs. Prescription drugs are often the therapy of choice and can be the most cost effective treatment. The affordability of prescription drugs directly affects the nature and quality of care available to patients. Dramatic increases in the costs of prescription drugs can have a deleterious effect on access to care and patient compliance with prescribed treatment.

Physicians' concern over the cost of prescription drugs has led our Association to call on the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The AMA also prepared a report on the increases in prescription drug prices during recent years. A copy of that report is included with this statement. In our report, we state that the AMA supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied:

1. Physicians must have significant input into the development and maintenance of such programs;
2. Such programs must encourage optimum prescribing practices and quality of care;
3. All patients must have access to all prescription drugs necessary to treat their illnesses;
4. Physicians must have the freedom to prescribe the most appropriate drugs for the individual patient; and
5. Such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs.

Ever since Medicaid prescription drug reimbursement has been identified as a primary target for cost-cutting and reform, there have been a number of proposals introduced to accomplish this. Some of these proposals have the potential to be truly dangerous to Medicaid beneficiaries and we strongly oppose them. Specifically, any Medicaid proposal which relies on the concept of therapeutic substitution should be rejected.

The practice of substituting a drug different in chemical structure from the drug prescribed by the treating physician has been applied in some institutions as a cost-containment measure. The risk of therapeutic substitution to the patient stems from the fact that different individual patients may react to a drug differently for reasons relating to their other medical conditions, to interactions with their other medications, and to factors such as the patient's age, race, and individual sensitivity. The risk is compounded if the substitution occurs in an outpatient situation where the physician has no idea that a drug has been substituted for the one prescribed. It is essential that the treating physician have accurate knowledge of the patient's drug therapy in order to monitor for possible therapeutic failure or side effects. Moreover, where drugs are substituted on the basis of whichever is cheapest, patients especially those with chronic disease may be switched repeatedly to a different drug after being successfully stabilized on the original drug.

The AMA expressed strong opposition to a recent Office of Management and Budget (OMB) proposal which would rely on a therapeutic substitution scheme as part of deficit reduction efforts. We understand that the Department of Health and Human Services (HHS), among many others, has also expressed opposition to the OMB proposal and modification of the proposal is likely.

Another approach to this issue is Senator David Pryor's "Pharmaceutical Access and Prudent Purchasing Act of 1990" (PAPPA), S. 2605. Senator Pryor has indicated that his primary concern is the increasing cost of drugs under the Medicaid program and the fact that drug costs are detracting from the ability of Medicaid to provide adequate reimbursement and coverage for other needed benefits. Of special concern to Senator Pryor is that Medicaid often pays higher prices for drugs than other high volume drug purchasers. The AMA shares Senator Pryor's concerns regarding the impact of prescription drug prices on Medicaid programs in the states.

The AMA has identified in S. 2605 several conceptual and practical problems, especially with the concept of drug interchangeability and the administrative processes that would burden the physician's practice with further administrative requirements. The AMA, therefore, does not support the bill as introduced.

Senator Pryor and the AMA have continued to discuss the legislation and are addressing the profession's concerns with the bill, although spontaneous actions by pharmaceutical companies may render the bill unnecessary.

Companies within the pharmaceutical industry also have responded with cost-containment proposals of their own. These proposals, in general, take a straight-forward economic approach and do not incorporate those elements such as therapeutic substitution that cause us concern with the quality of patient care for Medicaid beneficiaries.

Overall, we are generally encouraged that the parties to this issue appear to show genuine concern for the quality of care of Medicaid beneficiaries. We are also encouraged by the flexibility demonstrated by the parties to this debate.

Certainly the AMA would not support an approach that would result in a diminished or second-class level of care for the population served by Medicaid. We are confident that appropriate substantive reform and savings to the Medicaid program can be realized this year.

We would be happy to answer any questions you may have.

REPORT OF THE BOARD OF TRUSTEES

Report: 0
(A-90)

Subject: Cost of Prescription Drugs

Presented by: John J. Ring, MD, Chairman

Referred to: Reference Committee E
(Charles D. Sherman, Jr., MD, Chairman)

The affordability of prescription pharmaceuticals directly affects the nature and quality of care available to patients. Recent, and in some cases dramatic, increases in the cost of prescription pharmaceuticals have had a deleterious effect on access to care and patient compliance with prescribed treatment. During the 1989 Interim Meeting of the House of Delegates, Resolution 112 was adopted. Resolution 112 asks that the AMA urge the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The resolution also calls upon the AMA to study the justification for the sharp increases in prescription drug prices during recent years.

CONTRIBUTION OF PRESCRIPTION DRUGS TO HEALTH CARE IN THE UNITED STATES

The contribution of prescription drugs to improving the health of Americans and to containing the cost of health care is well recognized. Over the past century, new effective pharmaceuticals have helped in the virtual elimination of deaths in the United States from diseases such as poliomyelitis, pertussis, and tuberculosis and have contributed to a better than 30-year increase in average life expectancy at birth. Prescription drugs have been repeatedly cited by health economists as one of the most cost efficient of medical technologies.[1,2] Often self-administered and generally requiring no expensive medical facilities, drugs have increasingly replaced other more expensive forms of therapy, forestalling hospital admissions, shortening hospital stays and reducing the need for costly invasive medical procedures. Currently, prescription drug costs account for less than 7% of each dollar spent on health care in the U.S.[3]

Past House Actions: 1-89:301; A-88:273; I-85:229

THE COST OF PRESCRIPTION DRUGS IN THE UNITED STATES

The 1980s have witnessed a dramatic increase in the cost of prescription drugs. Between 1981 and 1988, the price of drugs in the U.S. rose 88%, a rate more than triple the general inflation rate of 28% for the period.[4] Although expenditures for prescription drugs represent only a small fraction of overall health care expenditures, the majority of drug purchases in this country are not covered by health insurance and must be paid for out-of-pocket by consumers.[5] For the poor, for persons dependent on high-priced pharmaceuticals for extended periods of time, and for the elderly living on fixed incomes who are major consumers of drugs, the cost of prescription drugs represents a major personal health-care expense.[6]

Since 1980, prescription drug prices have increased faster than general medical care prices and the prices of other goods and services (See Table 1).

Table 1: Consumer Price Index for Selected Goods and Services, 1980 - 1989

Year	All Goods and Services		Medical Care		Prescription Drugs	
	CPI-Urban	Percent Change	CPI-Urban	Percent Change	CPI-Urban	Percent Change
1980	86.3	13.6	77.6	11.0	75.2	9.2
1981	94.0	8.9	87.3	12.5	84.7	12.6
1982	97.6	3.8	96.9	11.0	94.9	12.0
1983	101.3	3.8	103.1	6.4	104.1	9.7
1984	105.3	3.9	109.4	6.1	114.4	9.9
1985	109.3	3.8	116.8	6.8	123.8	8.2
1986	110.5	1.1	125.8	7.7	134.9	9.0
1987	115.4	4.4	133.1	5.8	145.7	8.0
1988	120.5	4.4	142.3	6.9	157.1	7.8
1989	126.1	4.6	154.4	8.5	172.0	9.5

Source: U.S. Department of Labor, Bureau of Labor Statistics.

Approximately 50% of the increase in cost of drugs is attributed to the general increase in the consumer price index and about 3% of the increase is due to increases in the volume of drug purchases.

The remaining increase in the cost of drugs reflects increases in drug prices above the general rate of inflation and independent of prescribing practices.[7] Factors cited by the pharmaceutical industry as contributing to the rise in prescription drug prices include:

- the cost of research and testing including the cost of experimenting with drugs which did not prove to have therapeutic benefit;
- the cost of compiling clinical data and seeking and obtaining FDA approval;
- the cost of manufacture and production and of maintaining quality control;
- the cost of new drug promotion and physician education;
- the limits of patent protection and competition from generics;
- uncertain market life and competition from fast follower drugs;
- competition from overseas producers;
- product liability; and
- the need to provide adequate shareholder returns.[8-12]

DRUG RESEARCH AND DEVELOPMENT

A major factor driving the cost and, ultimately the price of pharmaceuticals is the high cost of drug research and development (R&D). A 1986 study conducted for the Pharmaceutical Manufacturers Association (PMA) estimated that it took, on average, 10 years and $125 million to get one medication from the laboratory to the pharmacist's shelf.[13] Preliminary data from a more recent study by Tufts University Center for the Study of Drug Development adds two years and more than $75 million dollars to the PMA's estimate of the lead-time and cost of developing a marketable drug.[14]

The profitability of individual drug firms depends largely on the continual introduction of successful new products. Thus, research and development is key to industry growth and survival. During 1989, U.S. drug companies reinvested nearly 17% of their pharmaceutical sales revenue ($7.3 billion) into drug research and development. This represented a 12.3% increase over the industry's 1988 R&D investment of $6.5 billion.[15] Pharmaceutical R&D funding has accelerated over the past decade, doubling every five years.[3,16] Yet despite one of the highest levels of R&D funding of any manufacturing industry in the United States, only a small proportion of this investment eventually results in saleable products.

Drug research and development is both expensive and risky.[17-20] R&D costs for new drugs can vary widely and there is no apparent relationship between the magnitude of these costs and success in the marketplace.[21] The Upjohn Company estimates that of every 2,000 chemicals studied by its laboratories, only 200 show any potential in early tests, and of these, only 20 may eventually be tested in people. Only one experimental drug out of the original 2,000 chemicals studied by Upjohn scientists may be found safe and effective enough to pass Food and Drug Administration (FDA) review and reach the market.[22] The PMA estimates the R&D success rate for new pharmaceuticals at an even gloomier one in 10,000.[9]

A major study of the cost of new drug development is being conducted by Tufts University Center for the Study of Drug Development under the direction of Joseph A. DiMasi, PhD, in collaboration with Henry Grabowski, PhD, of Duke University and Ronald Hansen, PhD, of the University of Rochester. The study, which is based on a 1987 national survey of pharmaceutical firms, examines in detail the actual expenditures by year and stage of development invested by participating companies in the development of new chemical entities. Results of this study are expected to be available by June or July of 1990.[23] The results will be communicated to the House of Delegates in a follow-up report on pharmaceutical drug pricing.

DRUG DEVELOPMENT AND THE FDA APPROVAL PROCESS

Compliance with FDA requirements for new drug approval adds to the cost of drug R&D in the U.S. Designed to help assure that only safe and effective medicines come to market, the FDA drug approval process formally begins with the filing of an investigational new drug (IND) application and culminates with the review and approval of a new drug application (NDA). For new drugs approved in 1989, the FDA required an average review time of 32.5 months just to review and take action on the NDA. However, years of basic research and laboratory and animal studies precede the submission of an IND and additional years of clinical trials in humans precede submission of the NDA. Even after the approval of the NDA, the FDA requires drug companies to continue to submit periodic reports that document adverse reactions to the drug, quality control records, and, for some drugs, long-term effects.[24]

According to W. Leigh Thompson, MD, group vice president of Lilly Research Laboratories, one of the major factors contributing to the rise in drug research costs is the increasing amount of information required to support new drug applications (NDAs) for the FDA--in particular "the expansion of the magnitude of clinical trials." Doctor Thompson illustrates this increase by pointing to the differences in clinical trial requirements for the 1979 approved antibiotic, Ceclor® (Cefaclor) and a similar related antimicrobial now under development at Lilly. While the clinical trials for

Ceclor® involved 1,493 patients, the clinical trials for Lilly's new antimicrobial will involve 10,000 patients. According to Thompson, the number of routine clinical laboratory tests have doubled every two years and the number of pages of clinical report forms submitted in NDAs have doubled every year and a half. The NDA for Lilly's recently developed Pindac (pinacidil), a vasodilator currently under review at the FDA is 470,000 pages in length.[25] "Technology inflation" has also played a part in the added cost of drug R&D as laboratories try to streamline basic research through the use of computer generated three dimensional molecular models.[26]

THE OUTCOME OF DRUG R&D

In 1989, 23 new drugs, i.e., new molecular entities (NMEs), obtained FDA approval and according to a recent PMA survey, there are currently 67 new drug applications (NDAs) awaiting FDA review in 1990.[27] The length and total cost of the research and development effort that resulted in the 23 FDA approved drugs in 1989 and that supported the 67 NDAs for 1990 are difficult to estimate. Drug manufacturers have argued that increases in pharmaceutical prices are necessary to cover the large and growing expense of research and development for new drugs.[28] Industry critics have countered that many of the new drugs coming out of this R&D effort offer little or no therapeutic advantage over existing products.[29]

In a majority staff report on the July 1989 Congressional Drug Pricing Hearings, the Senate Special Committee on Aging questioned the pharmaceutical industry's justification for high new drug prices based on high R&D costs and the value of drugs as new effective therapies. Using the FDA's evaluations of new drug therapeutic potential ("A" rated--important therapeutic gain; "B" rated--modest therapeutic gain; "C" rated--little or no therapeutic gain), the staff report concluded that class "C" drugs, those whose treatment potential was judged by the FDA to be essentially the same as existing drugs already in use, comprised 84% of the 348 new drugs marketed by the 25 largest drug companies between 1981 and 1988. Only 4% of this group of new drugs received an "A" rating from the FDA meaning they offered an important therapeutic gain over existing products. The report argued that Class "C" drugs, described as "me too" drugs, offer little economic advantages to the patient over existing drug products and, therefore, should be priced lower.[29] However, many of these new drugs are priced significantly higher than the older drugs they seek to replace.[30]

The PMA criticized the committee's staff report in their own report, "America's Pharmaceutical Research Companies:

A Cost-Effective Source of Important New Medicines." According to the PMA, the Senate staff analysis inappropriately lumped new molecular entities (NMEs), which account for approximately 80% of all industry research expenditures, with improvements to existing products, which almost invariably would be rated class "C" by the FDA. The PMA states that of 182 NMEs approved by the FDA between 1981 and 1988, 47% were considered to represent significant or moderate therapeutic gains.[28]

The PMA has also taken issue with the use of the FDA's rating system as a measure of the ultimate or even current value of drugs on the market. Designed only to serve as an FDA administrative tool to allocate reviewing resources, the rating system does not take into account that a drug's actual value to patient care evolves with widespread use.

Studies of new drug development show that many of the major pharmaceutical advances of the past 50 years have involved "me too" and "follow on" research.[29] These studies stress that "molecular modification is the essence of effective pharmacology" and the foundation of many original drug advances. For example, four important therapeutic classes of drugs--sulfonamide antimicrobials, diuretics, uricosurics, and oral antidiabetic agents--were ultimately derived from the drug prontosil, developed by Domagk in the 1930s. Molecular changes in mercaptopurine, a chemotherapeutic agent, led to allopurinol, a xanthine oxidase inhibitor used to treat gout, and azathioprine, an immunosuppressant; cocaine, an analgesic, eventually gave rise to the cardiovascular and anesthetic drugs procainamide, lidocaine, bupivicaine, and tetracaine; and research on norepinephrine's chemical structure led to alpha-methyldopa, an antihypertensive. A 1988 Tufts University study of the World Health Organization's essential drug list found that nearly half of the drugs considered essential by the WHO were not innovator drugs in their respective therapeutic classes but were the result of "me-too" and "follow-on" drug research.[31]

DRUG PATENT PROTECTION AND MARKET LIFE

Once a drug is on the market, the manufacturer prices the drug to recoup R&D costs and support ongoing operations. The market life of a new drug is uncertain. Competing manufacturers are continually introducing new products which they claim are as good as or better than drugs already on the market. Thus, at any time a more efficacious drug may appear and curtail an existing drug's market life even before the end of its patent life. Before a drug reaches the market, its patent life of 17 years is eroded by the length of its R&D period. The average remaining patent life for drugs after FDA approval is about nine years.[32] Once the drug goes off patent, it can expect competition from lower priced generic drugs.

GENERIC DRUGS

Since the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, the number of generic drugs developed has accelerated in the U.S. prescription drug market. The act facilitated quick FDA approval, via the Abbreviated New Drug Approval (ANDA) process, for generic drugs which were chemically equivalent and bioequivalent to FDA-approved brand name (innovator) drugs. (As a quid pro quo, the act also allowed manufacturers of innovator products to recoup some of the patent life lost on their drugs because of the length of the FDA's approval process.) Today, generic drugs comprise about 30% of U.S. retail drug sales.[33] Many of these generic drug products are manufactured by brand name drug companies. The share of the prescription drug market held by generic products is expected to expand as more brand name (innovator) drug products come off-patent (See Table 2)[34] and generic prescribing and generic substitution become more widespread.

Table 2: Major Drugs Losing Patent Protection 1991-1995.

Year of Patent Loss	Drug	Therapeutic Target	Manufacturer	Estimated Sales (in millions)
1991	Procardia	Heart	Pfizer	$228
	Tenormin	Heart	ICI	250
1992	Cardizem	Heart	Marion	300
	Ceclor	Antibiotic	Eli Lilly	191
	Feldene	Arthritis	Pfizer	208
	Seldane	Antihistamine	Dow	118
1993	Corgard/Corzide	Heart	Squibb	115
	Lopressor	Heart	Ciba-Geigy	169
	Naproyn	Arthritis	Syntex	275
	Xanax	Tranquilizer	Upjohn	235
1994	Tagamet	Ulcer	SmithKline	523
1995	Capoten	Heart	Squibb	207
	Zantac	Ulcer	Glaxo	500

Source: Generic Pharmaceutical Association as cited in Wall Street Journal, February 20, 1990.

Generic drugs often are much less expensive than the brand name (innovator) products they mimic. This price break is largely due to the fact that generic drug manufacturers do not incur the high risk and high costs of pioneering drug research and development. The major task of generic manufacturers is to demonstrate bioequivalence to the innovator drug product and secure FDA approval for their ANDA. Because the market for a generic product is already established by the brand name drugs they copy, the promotional and advertising budgets of generic drug producers are relatively small.

To compete with generics, brand name companies have chosen to raise rather then lower the price of their off-patent products.[35] The rationale is that there will be a post-patent period of continued brand loyalty among prescribers and patients. Although the number of sales of the brand name drug will fall as generics make inroads into the market, higher prices for the former may, for a time, offset market share losses to generic competitors.

Other strategies to retain market share in the face of generic competition include changing the appearance of the drug to increase patient recognition and brand loyalty, aggressive advertising compaigns which warn physicians of potential therapeutic inequivalencies of generic products, and modification in the drug delivery system which can potentially extend the patent life of the brand name drug. Pioneering drug firms also may establish or upgrade their own generic drug divisions to remain competitive in the therapy areas addressed by their brand name products. This strategy realistically accepts that brand name drugs, like other products, have a market life cycle and that the generic market will most likely become a permanent and growing part of the drug market. Generic substitution is permitted in all 50 states and a growing number of reimbursement programs either require or strongly encourage the use of generic drugs.[36] In 1990, only 21 of the current top 100 U.S. prescription drugs will have some form of patent protection.[32]

While competition from generic drugs has had the effect of boosting the price, at least in the short term, of specific brand name pharmaceuticals, increased use of lower cost generics in the place of brand name drugs should lower overall drug expenditures. Barriers to the growth of generic prescribing and substitution include physician resistance or indifference and physician and public concern over the quality of generic drugs.

DRUG PROMOTION AND MARKETING

Brand name prescription drugs are marketed directly to physicians. From a marketing viewpoint, it is important for a drug company to be the first on the market with a major drug innovation and to quickly develop brand name recognition for that drug within the medical community. Studies of physician prescribing practices consistently show that physicians are brand loyal.[7,37]

Advertising and promotional campaigns directed toward physicians are highly technical and often considerably more expensive than those directed toward the general public. The proportion of sales revenue devoted to product promotion is higher for drug manufacturers than for manufacturers of many other products. Because the pharmaceutical industry is continually introducing new products and responding to the claims of new competitors, advertising and promotional strategies must be continually changed and updated adding to the overall cost of drug promotion. As the prescription drug market has become more competitive, the promotional budgets of major drug firms have increased. In 1980, the U.S. pharmaceutical industry spent $754 million for promotion. The following year this figure increased 19% to $898 million.[38]

A large proportion of promotion budgets of drug companies are used to support the activities of field representatives or "detail men" who call upon physicians, pharmacists, and hospital purchasing agents. This one-on-one process is a very expensive way of advertising a product. Most drug companies believe that the size of detail forces directly influences market share. On average, 70% of drug company promotional expenditures are allocated to support sales forces. Between 1983 and 1989, the number of sales people at the top 30 most profitable U.S. drug companies increased 50%. By 1993, this detail sales force is expected to grow another 25%.[39]

INTERNATIONAL COMPETITION

Another factor affecting the pricing of drugs is international competition. Sixty-six percent of the total ethical pharmaceutical sales of U.S. drug firms in 1989 were domestic and 34% were foreign. The major foreign consumer of U.S. pharmaceuticals is Western Europe, followed by the combined market of Japan, Australia, and New Zealand. Anti-infectives comprise the largest class of drugs exported by the U.S.; cardiovascular drugs and central nervous system products rank second and third.[15]

There is a marked price differential between the cost of drugs in the U.S. and elsewhere in the world. The pharmaceutical industry has argued that much of the price differences by country reflect currency fluctuations. Other factors contributing to drug price differences between countries include variations in approval times between discovery and market entry, in standards of medical practice, in customary dosages, in packaging and wholesale and retail mark-ups, and in price control and drug reimbursement systems.[40]

Because the cost of R&D is lower overseas than it is in the U.S., a number of U.S. drug firms have begun to export this work. The length of the drug approval period also is much shorter overseas than in the U.S. Thus, a growing number of drugs submitted for FDA approval are already in approved use in Europe and elsewhere. Eighteen of the 23 new molecular entities (NMEs) approved by the FDA in 1989 were approved in another country first.[27] Differences between drug R&D in the U.S. and elsewhere in the world, differences in the financing of drug purchases, and currency fluctuations make a one-on-one comparison of drug prices between countries difficult.

PRODUCT LIABILITY

Another major difference that distinguishes the United States pharmaceutical market from many foreign markets is our product liability and tort system which adds to the cost of drugs in this country. According to the PMA, the number of product liability lawsuits filed in federal district courts has been increasing rapidly. Between 1986 and 1988, the number of cases in the U.S. district courts increased 26% from 13,595 to 17,104. Compliance with FDA drug approval regulations does not provide drug companies with immunity from product liability action.[13] A portion of the rise in drug costs represents the potential financial risks posed by product liability suits. Product liability considerations also have affected R&D. This is particularly true in the case of vaccines.[41]

DRUG PRICING AND THE ECONOMICS OF THE PHARMACEUTICAL INDUSTRY

To date, the pharmaceutical industry has resisted releasing detailed information on the pricing of drugs, considering this information to be proprietary. It is clear from a business standpoint, that the revenue realized through the sale of pharmaceuticals must support private drug research and development, marketing costs, manufacturing and distribution costs, and other operational expenses.

Critics of the industry have alleged that new drug prices are often 49% above the price of therapeutically comparable drugs already on the market.[42] High prices allow drug companies to recoup R&D costs in the early phases of a drug's product life. Premium pricing also acts as a market signal that the product is new, different, and presumably in some way better than the lower cost drug(s) it seeks to replace. As discussed above, premium pricing also occurs at the end of a brand name drug's market lifecycle when it goes off patent. Higher prices for newly off patent drugs allow drug manufacturers to capitalize on brand loyalty in the face of generic competition.

The pharmaceutical industry has been very successful in the pricing of its products and is today one of the most profitable and competitive industries in the country. United States drug sales increased 10.2% in 1987, 12.5% in 1988, and 13.1% in 1989. Foreign sales of U.S. drug companies increased 15.6% in 1987, 8.2% in 1988, and 8.4% in 1989. The pharmaceutical industry is thus one of the few major U.S. manufacturing concerns that is currently experiencing a positive balance of trade.[15]

In 1989, the pharmaceutical industry realized a 15.1% after-tax profit on sales, a return which was nearly three times the combined after-tax profit on sales experienced by all manufacturing enterprises in the United States that year. The after-tax return on stockholders' equity (RSE) has also been strong for the pharmaceutical industry. For the first three quarters of 1989, the after tax RSE was 28.6% for the pharmaceutical industry, nearly double the after tax RSE for all U.S. manufacturing (see Table 3).[43]

Table 3 : Pharmaceutical Industry and Manufacturing Industry Profitability, 1980-1989.

Year	Pharmaceutical Industry		All Manufacturing Industry	
	After Tax Return on Sales	After Tax Return on Stockholders' Equity	After Tax Return On Sales	After Tax Return on Stockholders' Equity
1980	13.2%	19.9%	4.8%	14.0%
1981	10.9	16.9	4.8	13.7
1982	13.1	19.7	3.5	9.3
1983	13.4	20.3	4.0	10.6
1984	13.3	20.2	4.6	12.4
1985	10.9	16.5	3.8	10.1
1986	14.5	22.9	3.7	9.6
1987	10.5	17.4	4.9	12.7
1988	16.0	30.4	5.9	16.0
1989	15.1	28.6	5.3	14.4

Source: Quarterly Financial Review as cited by G.S. Persinger, Assistant Vice President of Industry Studies, PMA, in January 26, 1990 letter to AMA Department of Drugs.

Despite the pharmaceutical industry's strong market performance, there are signs that it may be heading for more turbulent times. Since the 1970s the industry has been affected by a trend toward consolidation and takeover as drug firms worldwide seek to buy their way into new markets and acquire promising R&D ventures. The largest drug company worldwide is Merck with $5.9 billion in annual sales. However, Merck controls just 4% of the world market for pharmaceuticals.[26] The U.S. drug market is similar to the global market in that no single company dominates. However, as competition increases both within the U.S. and internationally, only the largest drug firms will have the resources necessary to support aggressive, long term R&D programs and expensive marketing campaigns (See Table 4).

Another signal of market change for the pharmaceutical industry is the fact that a number of drug products will lose their U.S. patents over the next five years. These include flagship drugs such as Pfizer's Procardia; Marion Laboratories' Cardizem; Eli Lilly's Ceclor; and SmithKline Beckman's Tagamet. According to Salomon Brothers analyst, Robert Uhl, by 1995, over $2 billion in domestic brand name drug sales for U.S. companies will be exposed to generic competition. Uhl and others have observed that there appear to be few new "blockbuster" drugs in the pipeline to replace these "star" products.[26]

The rate of drug innovation also appears to be slowing. The major health threats currently facing the U.S.--heart disease, cancer, neurological disorders, diseases of aging and viral diseases like AIDS have proved to be elusive therapeutic targets for drug R&D efforts. While some drug companies have continued to realize large returns on their R&D investments, others have been less fortunate.

DEMAND SIDE FACTORS AFFECTING DRUG PRICING

So far this report has reviewed many of the supply side factors that contribute to the rising cost and price of prescription drugs. These include research and development costs, competitive pressures, and the need to comply with FDA regulations. Demand side factors also affect the market for drugs and the way these products are priced. Demand side factors include physician prescribing and patient buying practices.

Prescription drug purchases are initiated by physicians who prescribe for patients. Physicians define the amount, frequency, and duration of a drug's use and whether a brand name or generic drug will be used. In states which allow generic substitution by pharmacists, it is still the physician who has the authority to

Table 4: Major Pharmaceutical Companies

Company	Country	Sales		Earnings (millions)	Return on Assets	R&D Expenditures (millions)	World Rx Market Share	
		Rx (millions)	Total (billions)				1983	1988
Merck	USA	$4,240	$5.94	$1,207	19.7%	$615	3.95%	3.80%
Glaxo Holdings	UK	3,160	3.52	976	22.4	404	3.0	1.4
Ciba-Geigy	SWZ	3,020	12.73	865	6.5	440	2.8	3.2
Hoechst	GER	2,700	23.53	973	5.3	330	2.5	3.0
American Home Products	USA	2,420	5.5	932	20.2	250	2.25	3.1
Bayer	GER	2,370	23.65	954	4.7	480	2.2	2.0
Johnson & Johnson	USA	2,350	9.0	974	14.9	385	2.2	2.3
SmithKline Beckman	USA	2,300	4.75	476	10.7	285	2.15	2.8
Pfizer	USA	2,260	5.39	791	11.4	380	2.1	2.9
Sandoz	SWZ	2,230	7.26	493	6.6	390	2.1	2.0
Eli Lilly	USA	2,090	4.07	761	14.5	375	1.95	2.5
Bristol-Myers	USA	2,010	5.97	829	16.0	275	1.9	2.1
Hoffmann-La Roche	SWZ	1,940	5.79	427	4.2	470	1.85	2.2
Squibb	USA	1,710	2.59	426	13.8	275	1.6	1.3
Schering-Plough	USA	1,670	2.97	390	12.3	300	1.55	1.7
Upjohn	USA	1,650	2.75	353	11.3	320	1.55	1.6
Warner-Lambert	USA	1,590	3.91	340	12.6	220	1.5	1.9
American Cyanamid	USA	1,560	4.59	306	6.7	190	1.45	NA
Takeda Chemical Inds	JAP	1,480	5.06	304	4.5	NA	1.4	1.1
Abbott Laboratories	USA	1,450	4.94	752	15.6	250	1.35	1.1
Imperial Chemical Inds	UK	1,450	21.06	1,586	18.1	240	1.35	1.6
Beecham Group	UK	1,400	4.68	458	10.5	140	1.35	1.4
Wellcome	UK	1,340	2.11	215	10.1	205	1.25	1.1
Rhone-Poulene	FRA	1,300	10.72	342	3.0	250	1.2	1.6
Sankyo	JAP	1,190	3.25	96	3.4	NA	1.1	1.4

Source: Financial World, May 30, 1989, p. 77.

insist on the use of a brand name drug. Although physician generic prescribing is on the increase, it still represents a relatively small proportion of all prescription orders. As noted above, barriers to generic prescribing include a lack of information or belief in the therapeutic equivalency of generic and brand name drugs, concern over the quality of generic products, and a lack of physician information regarding the availability of generic drugs.

In general, patients are even less informed than physicians about generic drug products. In addition, on the retail level, there is considerable variability in the price of prescription drugs, even within the same market area. According to a 1989 American Association of Retired Persons report on pharmacy surveys in the same community, the price of an identical prescription could be twice as much or more at one pharmacy as at another, and typically price differences of 25% can be found among half a dozen or fewer pharmacies in the same community. Furthermore, although, on average, generic drugs cost half as much as brand name drugs, generics at some pharmacies may cost more than their brand name counterparts at other pharmacies. The AARP survey also found substantial price differences for the same drug both within the same state and across states.[44]

Patients often do not comparison shop for prescription pharmaceuticals. If the price of a prescription drug is beyond their financial means, the patient may forego purchasing the drug or may take fewer pills than what is prescribed. The lack of insurance coverage for prescription medicine can be a significant barrier to quality care for many low and moderate income persons.

DRUG COST CONTAINMENT MEASURES

Most health insurance programs in the U.S. do not cover drug expenses and pharmaceuticals have not, historically, been the target of cost-containment measures.[7] Prescription drugs are covered by some HMO plans and state Medicaid programs. These programs, along with large institutional and group purchasers of pharmaceuticals, have been the innovators in drug cost containment.

Although prescription drug coverage is an optional benefit under Medicaid, 48 of 51 Medicaid jurisdictions provide this coverage. Faced with increased demands for services and limited budgets, state Medicaid programs have begun to institute policies aimed at containing the cost of drugs used by their enrollees. Medicaid program drug cost control strategies include:

- Restrictive formularies--lists of drugs that are approved for coverage;

- Copayment requirements--requirements that enrollees pay a part of drug charges;

- Maximum payment limits for all dispensed drugs--prescription drug payments capped at a fixed dispensing fee plus an amount to cover drug ingredient costs (usually the average wholesale price of the drug);

- Dispensing restrictions--limits on the amount of drugs that can be dispensed at any one time or on the number of covered prescriptions that can be reimbursed in any one month;

- Drug utilization review--formal review of the medical appropriateness and therapeutic implications of patient drug use.[7]

The effectiveness of these cost-containment programs has received mixed reviews.

Restrictive formularies are in use in about 20 Medicaid programs and are generally applicable only for outpatient drug use. Restrictive formularies limit program drug coverage to those drug products on an approved list. Limited or restrictive formularies allow Medicaid programs to channel most or nearly all drug purchases for a given therapy to a limited number of suppliers. This forces drug suppliers to compete on price. In exchange for price discounts, the supplier is assured a captured market for their drugs.[7]

Drugs are included in drug formulary lists based on the perceived needs of program enrollees, the therapeutic properties of the drugs, and their price. Drug formularies frequently consist of a set of lower-priced drugs which are felt to be therapeutically equivalent to higher-priced drugs. Drugs not on the formulary list are usually not eligible for Medicaid coverage although many state programs have prior authorization mechanisms which allow special exceptions to the closed list if a physician documents that an alternative drug is necessary for a particular patient.

Recent studies of Medicaid drug formularies have concluded that while these programs may reduce Medicaid drug costs, these cost savings are offset by the substitution of more costly services such as increased physician visits and hospitalization. The net result is that overall Medicaid costs may rise. A recent Louisiana State University study of restrictive Medicaid drug formularies, sponsored by the PMA, concluded that, on average, restrictive formularies may cause a 4 to 15% increase in a state's total Medicaid expenditures. The study found that patients who are prescribed less efficient, lower-cost drugs instead of restricted drugs may take larger amounts of the former or take these drugs for longer periods. Alternatively, these patients may be hospitalized. Inpatient hospital care costs for mental patients may rise 20 to 31% when this care is substituted for new drug treatments which are not included in the formulary. Restrictive formularies have also been found to exert strong upward pressure on the use of physician services raising Medicaid expenditures for this care by an estimated 28 to 37.6%.[45,46]

There is also growing concern that Medicaid formularies may compromise the quality of care provided to Medicaid recipients.[47] Medicaid patients may receive less than optimal care because of the inevitable time lag before new pharmaceuticals are reviewed and approved for inclusion in the formularies and because lower-cost, less-effective drugs which are included in these formularies may require a higher level of patient compliance to achieve the same therapeutic effect as off-formulary drugs. Not all studies of Medicaid formularies are so pessimistic about their potential to achieve program savings, but it appears that to be effective this cost-containment strategy must be part of a larger, more comprehensive program of utilization review and cost control.[46]

Another drug cost-containment strategy is the requirement of a patient copayment when a drug is purchased. Studies of these programs have consistently shown that they reduce drug program expenditures. However, the impact of these requirements on the utilization of other covered services and on overall Medicaid program expenditures has not been studied.[48] In an examination of drug cost containment strategies, Wagner and Duffy suggest that to the extent that copayment discourages consumers from filling prescriptions, it may negatively affect health outcomes.[7]

Medicaid drug costs have also been controlled through the use of maximum payment limits which cap the amount a Medicaid program will pay for any given drug. A special type of maximum payment program is the Maximum Allowable Cost (MAC) program. Federal regulations for the MAC program were issued in 1976. Over time these regulations have expanded to include price limits on a growing number of drug entities for which there are three or more suppliers. The MAC program sets ingredient price limits based on a review of the wholesale prices of all competing manufacturers of a given generic drug. State Medicaid MAC programs may include drugs in addition to those on the federal MAC list. Two major 1980 government sponsored studies of the MAC program concluded that it produced significant Medicaid cost savings. Although these studies have been criticized for not using a representative sample of states and drug products, for underestimating administrative costs, and for not examining the impact of MAC limits on other payors,[51] the MAC program has probably resulted in Medicaid savings particularly as more generic drugs have come into the market.

Dispensing restrictions either limit the quantity of drugs or the number of prescriptions that are covered by Medicaid for an enrollee in a given month.[7] Programs which limit the quantity of Medicaid covered drugs dispensed at any one time have been shown to save program expenditures. Programs which limit the number of Medicaid covered prescriptions in a given period have been shown to have the same impact as restrictive formularies--namely that while Medicaid drug expenditures may be lowered, there is an overall increase in total program expenditures because other health care services are substituted for prescription drugs. The health status of the elderly and the disabled, two patient populations characterized by the highest level of multiple prescription use, may also be seriously compromised by these programs.[7]

Drug utilization review programs have not been well studied.[7] Such programs, when appropriately designed, may improve the quality of patient care. Whether the administrative cost of these programs outweigh any drug cost savings is unclear.

Major private institutional or large group purchasers of pharmaceuticals including multihospital groups, HMOs, and pharmacy groups, have also instituted drug cost-containment measures. In addition to the aforementioned strategies, these private major drug purchasers have sought negotiated discounts from manufacturers and wholesalers in the price of drugs through group purchasing.

DRUG LEGISLATION

The pharmaceutical industry has vigorously resisted participating in drug cost-containment programs, particularly restrictive formularies, arguing that these programs reduce patient access to quality medicines and impede drug R&D. According to the PMA, drug "formularies undermine patient protection, and patent protection."[8,52] If companies agree to negotiate lower prices for drugs that are still on patent, the patent system itself will be undermined because the economic advantages of new drug discovery will be diluted.

Previous Congresses have supported legislation encouraging investment in drug research and development and drug patent protection. Examples of recent legislation supporting drug R&D and patent protection include the Orphan Drug Act of 1983 and the Drug Price Competition and Patent Term Restoration Act of 1984. In addition, the FDA has been encouraged to speed up the drug approval process. In 1987, the FDA revised its Investigational New Drug Application regulation and in 1989 the FDA permitted expedited review of new medicines for serious and life threatening diseases.[53]

A different attitude toward the pharmaceutical industry appears to be developing in the 101st Congress. The continuing rise in pharmaceutical prices and the impact these price increases are having on the cost of public health care programs and access to health care, has raised concern within Congress and the health care community about the cost and affordability of drugs in the U.S.[4] In July and November 1989, the Senate Special Committee on Aging held public hearings on the pharmaceutical pricing issue. At those hearings, Sen. David Pryor (D-AK), chairman of the committee, accused drug companies of charging "exorbitant prices" and turning out too few "breakthrough drugs" and too many "me too" drugs. Senator Pryor also announced his intention to introduce legislation to enable state Medicaid programs to institute measures which would allow them to achieve drug discounts and savings.[42] According to a Jan. 23, 1990, letter from the senator to the PMA, the proposed legislation will encourage Medicaid buying groups. Senator Pryor has also stated that the proposed legislation will not resort to restrictive formularies, but that lists of therapeutic alternatives will be necessary.[54]

Senator Pryor's bill is expected to generate lively debate about prescription drug pricing. Major points of discussion will include the role of government in drug cost containment, the dangers of therapeutic substitution in the out-patient setting, the effectiveness of drug formularies and other cost-containment programs in controlling health care costs, and the direction and value of current drug research and development efforts.

Representative Stark (D-CA) has also raised the issue of pharmaceutical price increases particularly in the area of vaccine prices. When Congress reconsiders drug R&D tax credits, which were extended through September 1990 in the Omnibus Budget Reconciliation Act of 1989, the issue of pharmaceutical pricing and the need for drug manufacturer R&D tax credits may be brought to the table.

CONCLUSIONS

Prescription drugs are among the most cost-efficient forms of medical technologies and, presently, they account for less than 7% of every dollar spent on health care in the U.S. However, over the past ten years, the prices of prescription drugs have increased faster than general medical services and have tripled the general rate of inflation for the period. Approximately 50% of the increase in prescription drug prices cannot be explained by the general increase in the consumer price index or by an increase in the volume of drug purchases and, thus, is directly related to price increases. The pharmaceutical industry cites a number of factors as contributing to the rise in prescription drug prices. These include rapidly rising R&D costs, lengthy FDA approval times, uncertain market life due to competition from fast-follower drugs, the limits of patent protection and competition from generic drugs, competition from overseas producers, increased product liability, and the need to provide adequate shareholder returns. However, during the 1980s, the pharmaceutical industry has consistently realized after-tax profits on sales that were two- to three-fold greater than the combined after-tax profits on sales experienced by all other manufacturing enterprises in the United States. Furthermore, the after-tax return on stockholders' equity for the pharmaceutical industry has consistently outpaced the after-tax RSE for all U.S. manufacturing.

Prescription drugs frequently are not covered by health insurance programs and the rapidly rising prices in prescription drugs can have a deleterious effect on access to care and on patient compliance with prescribed treatment. This is especially a problem for individuals with low to moderate incomes. For those insurance programs that do provide prescription drug coverage, including state Medicaid programs and some managed care (e.g., HMO) plans, drug cost-containment mechanisms frequently are introduced. However, the effectiveness of these programs in terms of maintaining high quality care and in their ability to reduce the overall cost of health care to the programs is questionable.

Growing concern about the cost of drugs and the effect on the quality and accessibility of care available to patients and increased legislative debate on strategies for containing public health care program expenditures for pharmaceuticals underscore the importance of the American Medical Association's involvement in this area.

The AMA will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the House of Delegates informed about the findings of these studies.

In addition, the AMA continues to work with the pharmaceutical industry to address patient access and quality of care issues which arise because of increases in pharmaceutical costs, lack of insurance coverage for pharmaceuticals, and R&D concerns. More work needs to be done to increase patient access to affordable effective drug therapies. The pharmaceutical industry must accept greater responsibility in the pricing of its products, looking not only to business concerns but also to the impact that increases in drug prices can have on the health care of patients.

The health care insurance industry should be encouraged to reconsider its limited coverage of needed pharmaceutical products which may substitute for more costly covered services. Physicians need better information regarding the therapeutic efficacy and equivalency of brand name drugs and generics. Patients need to be better informed about the variation in retail pricing of drugs and the role of generics in medical treatment.

To address these concerns, the Board of Trustees recommends that:

- The following policy statement be adopted:

  The AMA supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied:

  1) physicians must have significant input into the development and maintenance of such programs;

  2) such programs must encourage optimum prescribing practices and quality of care;

  3) all patients must have access to all prescription drugs necessary to treat their illnesses;

  4) physicians must have the freedom to prescribe the most appropriate drug(s) for the individual patient; and

  5) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs.

- Policy be reaffirmed supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encouraging physicians to supplement medical judgments with cost considerations in making these choices.

- Physicians be encouraged to stay informed about the availability and therapeutic efficacy of generic drugs. The AMA should assist physicians in this regard by regularly publishing a summary list of the patent expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products.

- Expansion of third-party coverage of prescription pharmaceuticals as cost-effective and necessary medical therapies be encouraged by the AMA.

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PREPARED STATEMENT OF JOHN A. GANS

My name is John Gans, and I am the chief executive officer of the American Pharmaceutical Association, the national professional society of pharmacists. APhA represents all areas of pharmacy practice. A guiding principle APhA has followed since our founding in 1852 is to advocate those principles which enable pharmacists to enhance the care of our patients. Quality patient care is the primary consideration for developing our position on this issue before us today. In the area of drug therapy, one only need to look at the record to see the reed for a more comprehensive system of providing it. Today, up to 20 percent of all hospital admissions can be traced to some kind of drug misadventure. It is therefore imperative that any drug program this country undertakes incorporate in it measures that will assure that patients use their medication properly. That is pharmacy's mission as well.

That is why we have found it so troubling to hear some opponents of S. 2605 sponsored by Senator David Pryor call the legislation "second class health care," when in fact it incorporates innovative measures that will enhance patient care. For example, one point of contention that opponents of the bill have cited is its use of therapeutic interchange. As a pharmacist who has practiced in community pharmacies, nursing homes, and hospital settings, I can assure the Committee that the concerns of the critics are unfounded. For years I worked with physicians using therapeutic interchange, and I have no doubt that it resulted in our selecting the best therapy for our patients. This practice called therapeutic interchange is not mysterious—it is simply the use of a formulary system or drug list to guide drug therapy, and it happens every day in organized health care settings throughout our nation.

Therapeutic interchange was developed by physicians and pharmacists working together. The essential component is a drug list or formulary, which these health professionals developed using the best scientific and clinical information available to them. Such formularies or drug lists are developed locally by joint committees of physicians and pharmacists, and they are tailored to conform with unique practice patterns and to meet patient needs as they exist in that particular system.

Subsequently, as therapeutic interchange became more widespread, there arose among manufacturers intense competition to get their drugs into the formularies, and that competition most often resulted in severe discounting of drug prices to individual hospitals, nursing homes and health maintenance organizations. But although a major result of therapeutic interchange has been cost-savings, one should never lose sight of the fact that its primary objective is not to obtain the lowest prices possible—it is to provide high quality patient care at the most cost-effective level possible.

Therapeutic interchange is a widely accepted component of drug therapy in the leading hospitals, nursing homes and MM0s throughout the nation. Most of you in this room who have received pharmaceutical care in the last 10 years from a hospital or nursing home in the United States have most likely had their therapy developed through the formulary and therapeutic interchange process. And now this concept has moved into the ambulatory care settings through health maintenance organizations and similar entities. For example, Kaiser Permanente—in which many Congressional staff members are enrolled—uses a formulary/therapeutic interchange process. Distinguished members of this Committee who have received their care at the National Naval Medical Center in Bethesda also have received the benefits of therapeutic interchange.

Therapeutic interchange is *not* second class health care as its critics claim. If it were, APhA could not support its use in the care that you, the leaders of our nation, receive or in the care received by Medicaid recipients who depend upon your leadership to meet their needs. We in the American Pharmaceutical Association fully support the practice of therapeutic intercharge in ambulatory settings, so long as it meets standards comparable to those in organized health care settings. We also feel strongly that this system can be adopted to the Medicaid program and will prove to be a significant improvement over the current system, so long as physicians and pharmacists—the health practitioners best trained and who are directly involved with their patients—control the process. This program would bring together the knowledge of both physicians and pharmacists and enable them to use their unique expertise—shared expertise in pharmacology, physicians' unique clinical experience, physicians' knowledge of their patients and their diagnoses, pharmacists' unique knowledge of patients' drug-taking habits, pharmacists' complete records of drugs taken, and pharmacists' daily knowledge of the comparative costs of drug products.

This active and cooperative process of therapeutic interchange brings about the best care for patients, while forcing a degree of marketplace competition to reduce prices. This fact has been well-documented by the Senate Aging Committee in its hearings over the last year. Therefore, we commend Senator Pryor and his staff for providing pharmacists a better opportunity to use their professional discretion to enhance the quality of care while reducing its costs, all in the best interests of the patients they serve.

There are a number of additional provisions in both S. 2605 and S. 3029 sponsored by Senator Pryor which also would enhance the level of pharmaceutical care offered to Medicaid patients. Senator Pryor's legislation calls for the opening up of all formularies in the nation to allow prescribers to utilize any FDA-approved drug for their patients. Senator Pryor's bill would put needed drugs on Medicaid formularies and leave the discretion of their use to health professionals. The same need for discretion should also apply to the generic use, especially drugs with narrow therapeutic ranges such anti-convulsants and asthma medications. Again, in organized health care settings the required interchange of the formulary system involving pharmacists and physicians has brought about the cost-effective selection of drug products which best suit the needs of the individual patient.

Another very positive provision of S. 2605 and S. 3029 which enhances patient care is the use of drug utilization review (DUR). APhA supports drug use evaluation as one element of a quality assurance program for medication use. Drug utilization review programs collate the total pharmaceutical care received by a patient, which is then reviewed by a group of pharmacists and physicians who compare that patient's therapy with national standards. When therapy deviates from those standards, the DUR group intervenes. DUR programs identify drug duplication, improper dosage levels, drug interactions, and other inadequacies of drug therapy. By identifying these problems early, a pharmacist can intervene before a patient may experience a drug misadventure which would require hospitalization or other high-cost care.

DUR programs were primarily developed as a quality assurance mechanism, but their record has proven that they also can yield significant cost savings. One study showed that for every one dollar invested in operating a DUR program, there was an overall cost savings of from three to five dollars.

All of this leads to a basic economic question. How can pharmacists be expected to engage in therapeutic interchange and DUR activities when both activities require the pharmacist to devote more time to patients without additional compensation? Mr. Chairman, it is well documented that pharmacy practice reimbursement has been cut significantly in recent years in order to compensate for dramatic increases in drug product costs. The additional time required by the pharmacist to perform therapeutic interchange and DUR activities and to provide patient counseling would even further extend the losses that pharmacists are now having to deal with under the Medicaid drug program. The proposals now before the committee—S. 2605 and S. 3029—would begin to restore these inequitable cuts in pharmacist reimbursement and to provide pharmacists with incentives to implement cost-saving measures. With your permission, Mr. Chairman, I would like to submit for the record a letter submitted on May 27, 1986 by APhA, several of the major pharmacy organizations, and the Pharmaceutical Manufacturers Association which calls for the same pharmacy reimbursement that is provided for in S. 2605. Mr. Chairman, S. 2605 and S. 3029 provide an artfully-drafted mechanism for producing hundreds of millions of dollars of savings for the Medicaid program while enhancing the quality of care to patients.

In addition, the legislation calls for demonstration projects to evaluate the impact on quality care and cost effectiveness that reimbursing pharmacists for their cognitive services would have. APhA believes strongly that recognition of the value of pharmacists' cognitive services will lead to improved care for the patient.

Another positive feature is the legislation's use of electronic claims processing procedures. Use of this up-to-date technology will facilitate administration, while curbing administrative costs.

The bill also focuses attention on another important area, prescription drug pricing. What I am referring to is a pricing strategy that is fundamentally unfair to the American taxpayer and to the American pharmacist—APhA calls it discriminatory pricing. Discriminatory pricing is the practice of many drug manufacturers, who, in order to assure that their products are included in the formularies of organized health care settings, significantly reduce their prices to these entities and then compensate for the lost revenue by charging significantly higher prices to the Medicaid program and private-paying patients. The Senate Aging Committee has well-documented this practice in the prescription drug industry. Nearly every pharmacist in this country has joined a large buying group in hopes of obtaining similar prices through volume buying. However, in most cases the prices obtained from manufacturers by these buying groups have not even approached those paid by hospitals, HMOs and nursing homes. Therefore, it is apparent that such discounts are not "volume" discounts. Even though many of these community pharmacy buying groups have been able to achieve comparable volume levels, the discounts they have been granted by manufacturers have not equalled those enjoyed by the organized health care settings. It is clear that volume is not the issue—these organizations get greater discounts because they use the formulary/therapeutic interchange process as an effective bargaining tool.

Senator Pryor's bill would address this inequity within the Medicaid program. However, these discriminatory pricing practices are not limited to the Medicaid program—they pervade the entire drug distribution system. As a result, all of your constituents who receive prescription drugs will be affected so long as drug manufacturers are permitted to shift the costs of drug products from one segment of the population to another. This practice not only encourages the dangerous diversion of drugs from accepted distribution channels, but it also places many American pharmacists at a competitive disadvantage that results in higher drug prices for their patients. We hope the Congress will examine the discriminatory pricing practices of many manufacturers and will assure that all Americans have equal access to drug prices. Senator Pryor's legislation calls for a much-needed report on drug pricing, and APhA agrees with the need for such a report.

In conclusion, Mr. Chairman, drug use in America has been extensively studied, and one of the disturbing findings has been the extent of misuse of medications and the number of medication misadventures that has resulted in hospitalizations. This problem is no less serious in the Medicaid population. Therefore, by utilizing the pharmacists and their skills, along with those of other health care professionals, the legislation proposed by Senator Pryor will help to significantly reduce this problem.

We appreciate your giving APhA the opportunity to speak on this Medicaid reform legislation. S. 2605 and S. 3029 are vitally needed legislation that comprehensively establish necessary reforms. We urge the committee to support this legislation to better serve both the Medicaid beneficiary and the American taxpayer.

Prepared Statement of Senator Orrin G. Hatch

Mr. Chairman, I appreciate the opportunity to appear before this committee to give you my perspective on various proposals relating to Medicaid prescription drug costs.

For many years, I have followed the issues of prescription pricing and the development of new therapeutic products. In 1984, I was privileged to be a part of the most significant efforts in recent history to obtain lower prescription drug prices for the American people. This law, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as "Hatch/Waxman," cleared away many of the legal and regulatory roadblocks to the marketing of low-price generic drugs.

A handful of bad actors in some generic pharmaceutical companies has created some temporary difficulties for the generic industry. Many corrections have been made administratively at FDA, and Senator Kennedy and I are working on additional legislation to provide the tools FDA needs so that such a scandal will not occur again. I am satisfied that, in the long run, the generic drug program will continue to help the American people obtain low-cost pharmaceutical products.

The so-called "Hatch/Waxman" Act has important bearing on this hearing today because it was developed to cut the cost of drugs without undercutting innovation. It provided consumers access to lower costs drugs that were bioequivalent to the pioneer drug once the drug was off-patent. It maintained incentives for pharmaceutical companies so that they would continue their investment in research and development that ultimately lead to better drug therapies for Americans. Consumers are the winners. They continue to benefit from important new breakthroughs in drug therapies and from access to lower priced drugs through increased competition in the marketplace.

Patents on more than 70 drugs, representing $5.5 billion in sales in the year 1985 alone, have expired since 1984. Because the market share of name brand drugs is reduced by upwards of 50 percent within two years of when patents expire, research-based companies have contributed significantly to lower health care costs. An independent drug analyst recently noted that brand name drugs with sales totaling about $10 billion are scheduled to go off patent between 1991 and 1995, which means increased competition is helping to reduce drug prices.

As you can see from this chart, within two years following the expiration of a patent, the pioneer drug commands only 51 percent of the marketplace, and competitive forces begin to reduce the cost of the drug. The Drug Price Competition Act of 1984 is working as an effective cost-control strategy.

As a matter of fact, virtually every state has implemented mandatory generic substitution programs that have saved Medicaid and other taxpayer-funded pharmaceutical assistance programs billions of dollars since 1984. Additionally, a large percent of Medicaid expenditures are for generic drugs rather than those that are considered sole-source drugs. Currently, Medicaid expenditures for generic drugs account for almost one-half of total prescription drug expenditures. This total amounts to a substantial savings in the Medicaid program, and perhaps we should consider a mechanism for "scoring" expected savings. However, such generic substitution should not be confused with therapeutic substitution that I will discuss later.

As ranking minority member of the Senate Committee on Labor and Human Resources, I have spent a considerable amount of time reviewing the drug development process. For a new drug to be reviewed and approved by the FDA, the manufacturer must produce a truckload of information concerning the composition of the drug, the results of clinical trials, and everything else required to ensure that the drug is safe and effective for the treatment for which it was created. These FDA regulations are necessary, but the process is costly and time-consuming.

Biomedical research is expensive. The equipment and buildings are expensive. The salaries for top-notch scientists and regulatory experts are high. The competition among different companies and even among nations is intense. The cost of developing a new drug has been estimated to be between $125 million and $231 million, and it is rising every year.

In many instances, such costs can never be fully recouped. For every 10 drugs entering the market, only three of these will ever recapture their development costs. Furthermore, for every compound that is commercialized, some 4,000 are abandoned in research. Drug prices reflect these and other business costs and risks. The competition among R and D companies is intense. Any proposal that artificially caps charges may harm the incentive to develop new therapies. I urge you to reject any legislative proposal that gives legal bias to one company's approach over another's or favors one firm over others, or indirectly favors development of drugs for certain diseases at the expense of drugs to treat other diseases.

Many of the current legislative recommendations are not sensitive to these issues. I agree that we must face the increasing costs of health care and the expanding Medicaid budget woes. Medicaid now provides health care to over 22 million people. Total funding for Medicaid has more than doubled over the last 10 years, increasing from $23.3 billion in 1980 to $48.7 billion in 1988. This increase has been due, in large part, to expansion of benefits and increased utilization. And, when you look at Medicaid prescription drug expenditures, it is projected that in fiscal year 1991, $5 billion will be spent.

I want to commend Senator Pryor for motivating Congress and the pharmaceutical industry to find ways of achieving important Medicaid drug savings. For the record, I believe his legislative initiatives helped provide the impetus for the negotiations that are currently underway with state Medicaid programs. I want to emphasize the importance of those discussions.

Reports are that 31 states have negotiated with various pharmaceutical companies for discounted drug rates, and 10 states are on the verge of signing up. I am pleased to report that my home state of Utah is one of them. We should encourage, not discourage, these negotiations. We ought to foster the ongoing efforts of states and manufacturers by finding a way to score the savings they will provide the Medicaid program.

We have learned from the Hatch/Waxman law that we can achieve real and substantial savings from market forces without distorting the delicate balance of innovation and regulation. These sage market forces have acted to provide discounts to other government health programs such as the VA, and there is no reason to believe they could not be harnessed to provide savings to Medicaid as well. Legislatively, we could score those savings that result from negotiations or contracts.

We should not enact S. 2605, S. 3029, and other similar proposals, because they not only hamper the current discussions but also because they rely on price controls, therapeutic substitution, and/or the development of formularies. These proposals, I believe, would reduce access and undermine the quality of care available to our nation1s poor and disabled, especially at a time when many of us concede that it is critical to expand and improve Medicaid.

I would strongly oppose *any* measure that contained therapeutic substitution. With generic substitution, the consumer is guaranteed a virtually identical product to the one prescribed. With therapeutic substitution, the patient gets a different product that has a different chemical composition, a different profile, different side effects, and different indications. Such substitution is bad health care policy and is opposed by a host of health care and public policy experts.

In addition, I encourage this committee to reject proposals that would force price controls on the Medicaid program. We need to assess the impact of such proposals' on the development of new drugs arid the impact on access to innovative therapeutic products for Medicaid recipients. But first, let us step back and measure the savings that current negotiations are producing and the savings realized from the "Hatch/Waxman" Act as more pharmaceuticals go off-patent. In addition, if there must be Federal intervention, let it be aimed at providing manufacturers with positive incentives for providing Medicaid discounts within the current competitive market framework.

Thank you for this opportunity to testify.

PREPARED STATEMENT OF ROBERT A. INGRAM

Thank you, Mr. Chairman and Members of the Subcommittee. My name is Robert A. Ingram. I am executive vice president for Glaxo Inc.

Glaxo Inc. is a United States pharmaceutical company that has its headquarters, research and development and manufacturing facilities in North Carolina. Glaxo employs more than 4,000 people and ranks among the three largest pharmaceutical manufacturers in the United States based on pharmaceutical sales. Glaxo concentrates exclusively on prescription medicines. Among our best known products are Zantac (ranitidine hydrochloride) an anti-ulcer medication; Ventolin (albuterol) an anti-asthma bronchodialator; Fortaz (ceftazidime for injection), an injectable antibiotic; Ceftin (cefuroxime axetil), an antibiotic for oral use, and Trandate (labetalol hydrochloride), for treatment of hypertension.

I appreciate this opportunity to discuss Glaxo Inc.'s discount proposal that is designed to make pharmaceutical products available to Medicaid beneficiaries.

Glaxo shares with other pharmaceutical manufacturers the conviction that all Americans should have equal access to the most effective drug products developed by medical science. We also are keenly aware that in many states, the poor of this country do not have the benefit of the most advanced medicines because fiscal constraints have resulted in restrictions on the availability of many medications. We are deeply concerned that cost pressures may lead to further restricted access in the future.

Glaxo has devoted considerable effort to finding ways that we as a pharmaceutical manufacturer can assist in alleviating the financial burdens on Medicaid and assuring access to medicines for the poor. We are here today because we are willing to provide the Medicaid system with significant cost savings.

Glaxo Inc. proposes to give to Medicaid the best discount on single-source pharmaceutical products that we offer to any nongovernmental entity that does not take physical delivery of our products; that is, the managed care industry. We have offered our discount program to every state that provides a drug benefit to Medicaid beneficiaries and have entered into contracts with a number of state Medicaid agencies to provide those agencies with the economic benefits of price competition in the managed care market. We are in the process of negotiating several such contracts. Glaxo believes that its market-based discount program takes advantage of marketplace dynamics to assure consistent savings to Medicaid both now and in years to come.

The "Best Price" Is Not a Realistic or Reasonable Reference Price for the Medicaid Discount

Before explaining Glaxo's proposal, I want first to explain why the so—called "best price" offered by pharmaceutical manufacturers to any customer, although an appealing phrase, is not a reasonable reference for discounts. Although the "best price" may be reasonable for a few companies, we believe for the industry as a whole, it is not a fair standard. For most manufacturers, the "best price" is the price provided to the Department of Veterans Affairs (DVA). Discounts to that market segment are a historical anomaly that has evolved from World War II efforts to bolster the government's access to needed medicines. Prices in that market have remained artificially low in part because companies like Glaxo have found it reasonable to give the veterans a break in a very small portion of our business. That segment represents only 1 or 2 percent of the total U.S. pharmaceutical market. Moreover, our prices to the DVA depot system are low because the Federal Government takes delivery and assumes responsibility for warehousing and distribution.

While some pharmaceutical companies' prices to the DVA are close to their commercial prices, for many manufacturers including Glaxo, the Federal prices are dramatically lower than prices we quote to any commercial customer. Testimony provided to the Senate Special Committee on Aging last year suggests that Glaxo is not alone in providing the DVA with deep discounts. Discounts listed on the Federal supply schedule, for example, according to a staff report of the Senate Special Committee on Aging, range from 41 to 67 percent off the average wholesale price for single-source drugs and 39 to 93 percent for multi-source drugs. These discounts would not be commercially reasonable for a broader segment of the market like Medicaid, which represents between 10 and 15 percent of prescription drug sales.

Companies that have provided generous discounts to the government in the past should not be penalized for doing so. If Medicaid discounts were pegged to the DVA price, companies that offer only small discounts or no discounts at all to the Federal government would be rewarded. By contrast, those companies that over the years have offered deep discounts to the DVA would be greatly disadvantaged. The result would be uneven and extremely unfair. Any legislation designed to ensure cost savings to Medicaid should affect each company equally. Glaxo believes that a discount based on a commercial discount to managed care organizations that do not take delivery of pharmaceutical products would be the most equitable and fair means to achieve this result.

Glaxo Offers a Market Based Proposal Designed to Preserve the Competitive, Marketplace While Providing Significant Savings to Medicaid.

Historically, third party payers have not been a significant factor in the pharmaceutical market. In recent years, managed care has become a growing and increasingly important competitive influence in the health care sector of the United States economy. The products of virtually every pharmaceutical company are sold in the managed care market at competitive prices set by the aggressive buying power of this growing sector.

In the, managed care industry, services are received by beneficiaries from health care providers and are paid for by a third party that contracts with providers. As a third party payer that reimburses for services of providers, the Medicaid system resembles managed care arrangements, such as network model and independent practice association model HMOs and preferred provider organizations. Managed care arrangements are the most analogous commercial customers to Medicaid for pharmaceutical manufacturers.

Glaxo's proposal is designed to provide Medicaid with the same level of discounts achieved in the managed care market by entities that are most like Medicaid in structure. Glaxo has offered to give to Medicaid agencies the best discount we give to those managed health care organizations that, like Medicaid, reimburse for prescription drugs dispensed by pharmacies to participant's in the managed care program. Under the Glaxo proposal, each state Medicaid agency would receive a discount from the manufacturer based on the number of units of a specific drug dispensed by pharmacies to Medicaid beneficiaries. In return, the states would be prohibited from imposing restrictions on beneficiaries' access to that manufacturer's products.

The Glaxo proposal gives state Medicaid agencies the benefit of the discounts obtained in the managed care market. Because this market is substantial and growing, it is highly successful in achieving competitive contracts with manufacturers. Some single Independent Practice Association model HMOs, for example, are even larger than California's Medi-Cal, the largest state Medicaid program. In view of the continuing development of the managed care industry, Glaxo believes that as a proxy for Medicaid programs, managed care organizations will obtain significant; discounts for the states without creating the need for additional Federal or state administration to negotiate prices.

Glaxo's discount proposal, because it is referenced to contracts with the managed care industry, makes it difficult for manufacturers to withdraw or raise prices to Medicaid in future years. Discounts for the managed care industry are assured by contracts of several years duration. The most competitive managed arE organization will get the best discounts lasting for three to five years. Because those discounts are the reference for Medicaid contracts, we expect that discounts to Medicaid agencies would be assured until a more competitive managed care organization succeeds in getting an even better discount.

We propose that the states remain free to use formularies and prior approval requirements for products whose manufacturers do not offer discounts to Medicaid agencies. Thus, while skeptics claim that manufacturers may withdraw these "voluntary" discounts in future years, withdrawal would subject the manufacturer to the risk of losing a sizable portion of its business when the state excluded the drug from its formulary. In this way the state would retain considerable leverage to induce manufacturers to offer discounts.

The Forces of the Marketplace Offer Significant Savings for Medicaid.

Our proposal could result in significant savings for Medicaid. Our discounts in the managed care market range from 5 to 20 percent on some products. A fair assumption is that the market as a whole would yield an average discount on Glaxo products of approximately 15 percent. Our proposal does not add administrative costs to Medicaid. Any cost increase resulting from our proposal derives from the access-enhancing requirement that manufacturers' discounts be matched by states' guarantees that beneficiaries will have access to all discounted drugs.

A discount referenced to contracts with the managed care industry would provide savings to Medicaid agencies without distorting the incentives for innovation provided by the free market. Manufacturers depend upon the market system to reward the most innovative and effective products and to determine which products offer clinical advantages over existing products. Because our proposal allows the commercial market to set the discount levels for Medicaid, competition and the incentives for innovation provided by the free market would be preserved.

The Federal Government Should Set Guidelines for Savings by the States.

Increasing numbers of states have achieved significant savings to Medicaid this year by successfully contracting with manufacturers. As stated above, Glaxo is entering into contracts with state Medicaid programs that will result in significant savings to the states and to the Federal Government. Moreover, we understand that the states are having considerable success in achieving cost savings for Medicaid in contracts with manufacturers besides Glaxo. According to news reports, at least 11 companies are currently negotiating with states. These companies produce many of the most significant therapeutic advances in medicine in the world today. Because there is so much activity in the states, Federal legislation may not be necessary at all at this time.

Glaxo believes that the goal of cost savings to Medicaid could be most appropriately achieved through our discount proposal. However, we recognize the difficulty Congress faces in choosing among the various proposals. Given the level of activity by the private sector and the states, Federal legislation may not be necessary, at least at this time. Congress has already performed the extremely important job of calling the problem of Medicaid costs to the attention of the pharmaceutical industry. Glaxo and others have responded.

At this point, the wise course is for Congress to continue to harness the energies and the diversity of the private sector and the 50 states—and not to impose from above a confining formula that would stifle creative efforts to solve the problem.

Thus, we suggest that Congress issue a broad legislative directive to the states to achieve savings in the state drug budgets during the coming year. Such a directive would allow each state Medicaid agency to achieve savings in ways most appropriate to the individual state. Each state could be directed by Federal legislation to demonstrate the amount of its savings to the Federal Government. Such a federally directed mandate would be entirely consistent with the premise of Medicaid that the Federal Government establish guidelines to be implemented by the states in keeping with the circumstances and particular needs of each individual state.

A final concern is that Federal legislation might not preserve the existing contracts between states and pharmaceutical manufacturers. These contracts have been negotiated with the states in good faith and should not be upset by a subsequent Federal law. Should Congress pass Federal legislation, that legislation should include a "grandfather clause" that would preserve any existing contracts with manufacturers that contribute to overall savings to Medicaid.

As stated above, Glaxo favors providing the Medicaid system with significant cost savings. At the same time, we do not believe that any legislation that would be tantamount to price controls is in the best interests of the American public. Such controls would be contrary to the principles of the free market and may inhibit the discovery of new and important medicines by the research-based pharmaceutical industry.

In keeping with the fundamental principle of Medicaid as a health care reimbursement system for America's poor, again we maintain that any discounts the states obtain from manufacturers must be linked to assurances that physicians will be able to determine when a particular medicine is appropriate for medical care and to prescribe that medicine without restriction. In the rush to achieve savings, we must not lose sight of the overriding objective to provide equal access to the best advances in modern medicine to all people regardless of the method of payment for health care services.

Prepared Statement of Alphonse Jackson

Mr. Chairman, for several years now I have been honored to serve as Chairman of the Health and Welfare Committee of the House of Representatives in the Legislature of the State of Louisiana. As Chairman and, of course, as a member of the committee before that, I had already heard every argument and every proposal that has been laid out before your distinguished Committee. That is because the argument over the economics of the Medicaid prescription drug program has flared again and again at the state government level—not just in Louisiana, but also in most other states.

The debate inevitably develops along the same lines that are being argued here. on the one hand, there are those who believe it is quite unnecessary to make all medications available to America's poor—that a relatively short list of cheaper prescriptions will be adequate. They argue that by not spending money for more expensive medicines the government will save money. On the other hand, others have long thought that America's policy in this area should simply be to provide the poor with the best medication available. For example, they ask, "Would we, as Legislators, restrict ourselves and our families to that same short list of cheaper prescriptions?" They also claim that overall Medicaid costs will increase if the short list, which is called a restrictive formulary, does not provide the proper medication for the individual. It seems obvious, they say, that hospitalization resulting from a lack of proper medicine, will cost a lot more than helpful medication.

While this debate might be intellectually and emotionally stimulating, we can no longer argue endlessly. The budget crisis at both State and Federal levels demands a revolution. Mr. Chairman, as we approach the making of that resolution, we must act wisely. If we do not make the best possible fiscal decisions about the Medicaid prescription drug program, we will not only hurt a lot of poor people, we will also waste an enormous amount of Federal and State revenues. The time for resolution of the Medicaid prescription drug debate at the Federal level might be near, but in Louisiana it has already come and been dealt with. We undertook one of the most thorough studies of the economics of the program ever made, and passed legislation that after just one year has already begun bearing positive results. Perhaps an explanation of the steps we took, along with a description of why we had to take them, would be useful to this Committee.

In terms of hardworking people, abundant natural resources, clean and attractive cities, and a beautiful countryside of lakes, rivers, forests and fields, Louisiana is one of America's richest states. Even so, we have for the past few years suffered a terrible economic depression. At a time when our national economy grew continuously, and the stock market index climbed to the 3,000 mark, my home state was marred by economic devastation. The collapse of oil prices in the middle of the past decade bankrupted businesses, threw tens of thousands out of work, and reduced the ability of the State to raise revenues.

At a time when the cost of a middle class home rose to a quarter of a million dollars and more on the coasts of the eastern and western United States, we in Louisiana experienced unemployment of more than twenty percent. Ours was a state that for years had been well financed. But, suddenly, precisely when the needs of our people for government assistance became greater than at any point in modern times, we in the Legislature found that we had lost much of our ability to provide government assistance. Proportionately, our budget deficit was not unlike that with which you are struggling here at the Federal level. At that time, Medicaid, largely funded by the United States government, became the only source of medical care for hundreds of thousands of Louisianians. Personally and on behalf of my State, I thank those of you who have consistently supported Medicaid. It has been the difference between life and death for many.

Even with Federal assistance in many areas, our State budget was extremely limited—not least of all Medicaid. we found it necessary to reduce costs everywhere possible, to look at every area of State spending. Thus it was that we turned once again to the debate over what drugs should be made available to the poor. As you know, until the proposals before this Committee were introduced, the number and quality of medicines authorized for Medicaid have always been the prerogative of the States. I believe it should remain a state prerogative, and will explain why later in my testimony. But, first, let us review what we did in Louisiana.

Faced with the need to cut State spending, I introduced in 1988 the legislation that gave Louisiana one of the most restrictive formularies in the nation. The list had already been pared by previous Legislatures. My bill cut another 200 drugs from it. Thus, we created an extremely restrictive formulary—but, even so, it was not as restrictive as the formulary proposed by Senator Pryor and the Office of Management and Budget.

After less than a year, It became apparent that our effort to save money was turning Into a disaster—a nightmare for the Louisiana poor, whose ranks were growing remorselessly as the depression, tightened—and a calamity for the Medicaid budget. Costs for services stimulated by the lack of appropriate medication, skyrocketed. By the time the 1989 session of the Legislature convened, we knew something had to be done.

As a first step, along with my counterpart in the Senate, I co-chaired joint hearings in seven cities. Doctors, nurses, patients, nursing home operators, hospital administrators, volunteer health organizations, and representatives of both business and labor condemned our restrictive formulary. Their remarks furnished countless examples of how our policy was failing.

For instance, a physician from Monroe told us about a young man who had suffered a leg wound. Our formulary did not provide adequate antibiotics. Within 10 days after leaving the doctor's office, this young man showed up in the emergency room suffering from blood poisoning and delirious with fever. He spent six days in intensive care, and another 20 days in the hospital. The medicine he required would have cost Medicaid $40 or $50. Instead, his hospital bill alone totaled more thin $15,000. The only good news was that his leg and his life wore saved.

This kind of story was told repeatedly. However, even though our restrictive formulary policy had no doubt backfired in some Individual cases, we were not convinced that it was to blame in the broader sense. In other words, while an individual case could be disastrous, we realized it was still possible that our policy taken in the aggregate might still be economical.

Working from a grant by the Pharmaceutical Manufacturers Association, professors from the Department of Economics at Louisiana State University produced what has since been called the strongest study ever made of restrictive formulary economics. Professors Robert Newman and William S. Moore found with an extremely high degree of probability that restrictive formularies add 4.1 to 15.5 percent to overall Medicaid costs. A later study by Vanderbilt University economist Frank Sloan confirmed the scientific reliability of the LSU study, then went on to review all other known studies on the subject. According to the Vanderbilt study, no money has ever been saved through the use of a restrictive formulary.

Given these facts, the Louisiana Legislature passed a law that eliminated our restrictive formulary. My counterpart in the Louisiana Senate and I were the authors of that legislation, even though one year earlier we had authored the law creating the restrictions. As legislators, we found this pill hard to swallow but the facts of the matter left us no choice. The restrictive formulary that we had been instrumental in creating had to go. It did so by a vote of 96–0 in the House, and 34–1 in the Senate. Governor Buddy Roemer signed the measure into law.

Now the question is, what was the result? Mr. Chairman, during the past year—our first with an essentially open formulary (we still restrict cosmetic drugs)—Louisiana added about 30,000 people to the Medicaid roles.

In spite of increased numbers of Medicaid recipients, the overall Medicaid Coat for prescription drugs did not exceed the budgeted amount for the Medicaid prescription drug program. While the data is based on only 12 months of experience, the trends suggest that the Louisiana open formulary concept will save our state additional dollars in terms of reduced doctor visits, emergency room care and reduced acute and long-term health care costs.

Based on the experience in Louisiana, S. 2605 and the O.M.B. Proposal will not save money but may add substantially to the overall Medicaid cost throughout the nation. It is my belief based on the experience in Louisiana, that an open formulary that would guarantee physicians the right to prescribe the medicine best suited for a patient would reduce overall Medicaid costs. While the goal to reduce cost is not only laudable but essential to balancing the Medicaid budget, we must exercise care not to embrace and implement by Federal laws and policies a health care program for Medicaid patients that could produce a scheme of second-class medicine for the poor and end up costing money, instead of reducing health care cost.

Mr. Chairman, pharmaceuticals are cost-effective. They represent less than seven (7) percent of the overall Medicaid cost. Real savings are being realized from the recent breakthroughs in the industry as it relates to treatment modalities. For example, if we can find a cure for Alzheimer's disease, untold millions will be saved.

Mr. Chairman, the research suggests that real savings will be realized if we can find ways to reduce acute and long-term care.

Mr Chairman, it is imperative that the pharmaceutical industry continues extensive research to assist in curtailing health care cost.

Mr. Chairman, having explained how Louisiana has suffered under the restrictive formulary but prospered under a vastly open list of medicine for the poor, I must sadly turn to another consideration.

Mr. Chairman, America's minorities constitute a disproportionate share of the nation's destitute—the people who by and large make up the Medicaid rolls. In Louisiana, for example, Black people make up less than 30 percent of the population, yet some 70 percent of all Medicaid recipients are Black. When news of Senator Pryor's bill and the O.M.B. Proposal reached the Black community, great concerns were voiced to leaders in the health care field in Louisiana.

Mr. Chairman, it is with great sincerity that I must advise you that many poor people see these proposals as measures that will prevent them from receiving proper health and medical care. I believe that the authors are well-intentioned in trying to save money, but ill-advised on these proposals as a means to reduce coat.

As I noted earlier, decisions as to what drugs to make available to Medicaid patients have always been left to the States. With all due respect, Mr. Chairman, we State legislators are like our more distinguished representatives to the Congress — extremely concerned about costs. As I have just described, we too must deal with fiscal crises.

Thus, I do not see the necessity for the Federal Government to take control of the Medicaid prescription drug program in order to reduce costs. In fact, if the proposals of Senator Pryor and the O.M.B. are enacted, proven and established methods of the States would be abolished in favor of more costly programs. Perhaps more importantly, we should recognize that different sections of this vast country of ours have different health problems. For example, geography alone causes different ailments, and requires different treatments for people who live in such widely diverse areas as Montana and Louisiana. The establishment of a national body which would determine one highly restrictive list of medicines for all, regardless of local conditions, would lead inevitably to worsened health in all areas.

Finally, it is true that the cost of medicines has gone up in recent years—and my purpose is not to defend those increases. Now, some companies are offering to sell States drugs at discount. So long as their offers do not develop into restrictive formularies, this might be a way to achieve real savings. However, to the extent that drugs continue to be restricted—that only discounted drugs are made available—we will continue to lose money. I suppose you could call such a perversion a "Discount Restricted Formulary."

In summary, Mr. Chairman, I have described our experience in Louisiana—where we have already learned the hard way that restrictive formularies hurt people and cost more than they save; the discriminatory aspect of the proposals advanced by Senator Pryor and the O.M.B.; the need to keep decisions about the Medicaid drug program at the State level; and the need to make certain that proposals by drug manufacturers are not twisted into new forms of restrictive formularies. I strongly recommend that this entire matter be sent to the appropriate Congressional committees for deliberation and inquiry. Certainly, it is far too important and inflammatory to be rushed to judgment as part of the annual budget.

Thank you.

PREPARED STATEMENT OF GERALD J. MOSSINGHOFF

Mr. Chairman and Members of the Subcommittee: I appreciate this opportunity to appear before the Subcommittee on Health for Families and the Uninsured to discuss with you the important subject of modifying Medicaid's drug-reimbursement program. With me today are Theodore Cooper, M.D., Ph.D., Chairman, President and Chief Executive Officer of The Upjohn Company; John L. Zabriskie Jr., Ph.D., President of Merck Sharp & Dohme; Robert A. Ingram, Executive Vice President for Administrative and Regulatory Affairs of Glaxo Inc., and M. Kenneth Bowler, Vice President of Pfizer Inc.

In my prepared statement I will discuss Senator Pryor's proposed legislation, S. 2605, and the reasons why PMA and dozens of patient groups, voluntary health organizations, medical societies, and state and-Federal legislators oppose its enactment. I will also outline the reasons underlying the strong opposition to an OMB Medicaid proposal for therapeutic substitution that was sent to the Budget Summit negotiators on June 20. Several of our member companies are now negotiating rebates and discounts in the states, and four PMA companies—Merck, Glaxo, Pfizer, and Upjohn—have made proposals to achieve savings in the Medicaid prescription-drug program that will be briefly summarized. Finally, I will comment on H.R. 5589 and S. 3029, which were introduced last Wednesday.

Attached to my statement (Attachment 1) is a pamphlet published by PMA on "Medicines in Medicaid," which provides basic data on the research-based pharmaceutical industry's contribution to Medicaid patients. In the interest of time, I will only make four observations regarding prescription drugs in the United States:

(1) Single-source or patented drugs amount to only $1.5 billion of the estimated $5 billion cost of Medicaid prescription drug coverage, less than multiple-source drugs ($1.9 billion) and pharmacy markups and dispensing fees ($1.6 billion).

(2) Our recent analysis of the largest Medicaid program, California's Medi-Cal program, shows that over 60% of the increase in drug expenditures from 1984 to 1989 was due to increased utilization, not the cost of prescriptions. Increased utilization has resulted from expansions in Medicaid eligibility and an increased number of prescriptions per Medicaid patient. Increased use of prescription drugs by Medicaid patients is consistent with the general shift of patients from in-patient to lower-cost out-patient care, and the wide-spread recognition of the cost-effectiveness of prescription drugs.

(3) Although the overall cost of medical care in the United States has represented an ever-increasing share of GNP, prescription drugs have claimed less than 1% of GNP for the past 25 years. The percentage was 0.84% in 1965 and 0.86% in 1988, the last year for which Health Care Financing Administration data are available. While claiming a small and remarkably constant percentage of the U.S. GNP, America's research-based pharmaceutical industry has established itself as a world leader in high technology, one that has consistently enjoyed a positive trade balance.

(4) Over the past six years, PMA member firms have contributed to substantial Medicaid program savings as a result of the streamlined generic approval process of the Drug Price Competition and Patent Term Restoration Act of 1984. More than 1800 Abbreviated New Drug Applications have been approved by the Food and Drug Administration since the enactment of that law, providing generic competition to a significant portion of the brand-name market. The brand-name products typically lose half of their market to generic competition within two years after patent expiration. Savings as a result of increased generic competition will continue. An independent drug analyst recently noted in *Investors Daily* that brand-name drugs with annual sales of $10 billion are scheduled to go off patent between 1991 and 1995.

S. 2605

Since the introduction of S. 2605 on May 10, 1990, dozens of leading patient groups, voluntary health organizations, medical societies and key policy—makers have voiced vigorous opposition to its enactment. Lists of those who oppose enactment of S. 2605 are attached to my statement as Attachments 2 and 3. Those listed in Attachment 3 have stated their opposition both to S. 2605 and to the OMB proposal.

The statements, of course, speak for themselves, and although they are voluminous, I respectfully request that they be included in the record of this hearing. Given the stature of the many organizations and individuals expressing strong opinions and the fact that they represent millions of Americans, I would submit that their views should be considered by the Subcommittee in its deliberations.

Essentially, the opposition to S. 2605 is based on the following reasons:

- An inherent flaw in S. 2605 is in its underlying premise that entirely different drugs having unique chemical structures are somehow therapeutically interchangeable among patients who have vastly different medical profiles.
- A result of S. 2605—indeed its intended result—is that drug therapy in Medicaid would be chosen by low-bid, not by the medical judgment of the patient's physician. The bill would thus result in second-class medical care for Medicaid recipients.
- The cumbersome pharmacist-to-physician call-back system of S. 2605 would undoubtedly lead to two lines at the pharmacist's counter: one where prescriptions would be filled promptly and a second Medicaid line of persons waiting for the pharmacist to exercise "diligent efforts" to reach the physician to get permission to substitute a low-bid drug for the one originally prescribed.
- The "three-day-supply" provision of S. 2605 would force Medicaid patients to return to a pharmacy in three days if, as would happen in hundreds of thousands of cases, the pharmacist could not reach the physician after "diligent efforts. Considering the fact that only an estimated 10% of Medicaid patients have independent

means of transportation, this provision would be extremely burdensome, particularly in rural areas.

- The significant costs of administration involved in S. 2605—which according to the Congressional Budget Office would involve an additional 1,000 Federal officials and 1,000 state employees—would more than offset any possible "savings" from substituting low-bid drugs.

S. 2605 is an extremely complex bill and to discuss it thoroughly would require far more than the time allotted to me this morning. I have attached to my statement the following documents:

> Attachment 4—A legal opinion from Lloyd N. Cutler, Esq., stating his views that the closed-door process of selecting "therapeutic alternatives," which would be required by S. 2605, would be unconstitutional;
>
> Attachment 5—A letter from the law firm of Sidley & Austin commenting on the increased professional liability exposure for physicians that S. 2605 would cause, and
>
> Attachment 6—A May 22, 1990 "White Paper" setting forth PMA's detailed comments on S. 2605.

THE OFFICE OF MANAGEMENT AND BUDGET'S JUNE 20 PROPOSAL

As part of the Budget Summit efforts, the Office of Management and Budget proposed a scheme for savings in the Medicaid program that went well beyond S. 2605. Instead of requiring the pharmacist-to-physician call-back of S. 2605 before the low-bid drug could be substituted, the 0MB proposal would require naked therapeutic substitution. Unless the physician wrote that the prescribed drug was "medically necessary," the pharmacist would be required to dispense a low-bid drug consisting of an entirely different active chemical from the one prescribed, without the knowledge of the physician or the patient. Recognizing the real dangers inherent in its proposal, OMB would hold pharmacists, but not physicians, harmless from resulting injury or death to the patient. As pointed out in a joint statement by the American College of Cardiology and the American Heart Association, therapeutic substitution represents "a real and present danger to individual patients."

To my knowledge no one has supported the OMB proposal. A list of those who issued statements vigorously opposing it is attached to my statement (Attachment 7). Again, since these statements speak for themselves, I respectfully request that the statements themselves be made a part of the hearing record.

COMPANY PROPOSALS

Four leading research-based pharmaceutical companies—Merck, Glaxo, Pfizer, arid Upjohn—have each proposed Federal legislation. As the Subcommittee requested, I will briefly summarize each of the four company proposals in their terms:

Merck

> "Under the Merck plan, called the Equal Access to Medicines and Best Price Discounts Act, manufacturers would be required to grant best price-based rebates on all of their single-source prescription drugs to every state's Medicaid program as a condition for reimbursement. Such rebates would equal the difference between the manufacturer's price to wholesalers and its 'best price' offered to any U.S. purchaser. The minimum discount required under the Merck plan would be 10%.
>
> "The Merck plan would assure Medicaid patient access to a full range of pharmaceutical therapies by prohibiting states from using formularies, prior-authorization requirements, or any other restrictions on the single-source prescription drugs of those manufacturers that provide rebates.
>
> "The Merck proposal further calls for a ceiling on discounts that would be phased-out over a five-year period. Specifically, the ceiling would be 15% in the first two years, 20% in the third and fourth-years, and 25% in the fifth year. There would be no ceiling in the sixth and subsequent years.
>
> "Merck voluntarily announced the plan to the states in April. Since then, 32 states have adopted it and ten more have declared their intention to embrace it. These 42 states account for over 90% of all Medicaid drug expenditures in the nation."

Glaxo

> "Glaxo's proposal is designed to provide Medicaid with the same level of discounts achieved in the managed-care market. Glaxo has offered Medicaid agencies the best discount it gives to those managed health-care organiza-

tions that, like Medicaid, reimburse for prescription drugs dispensed by pharmacies to participants. Under the Glaxo proposal, each state Medicaid agency would receive a discount from the manufacturer based on the number of units of a specific drug dispensed by pharmacies to Medicaid beneficiaries. In return, the states would be prohibited from restricting access of Medicaid beneficiaries to the manufacturer's products."

Pfizer

Turning to the Pfizer proposal, it has five key elements:

"Manufacturers would be required to make quarterly Medicaid Discount Payments to Medicaid programs in amounts that assure that the programs receive the best market price available in the U.S.

"Effective October 1, 1992, states that reimburse prescription drugs would be required to reimburse all sole-source drugs with no requirement for prior authorization.

"The Federal Government would not be permitted to establish a Medicaid formulary.

"All sectors of the marketplace for prescription drugs should contribute to Medicaid savings. Possible options for multiple-source drugs include: codify the current HCFA regulations (150% of the lowest priced drug product), use the same 'best-price' formula as proposed for sole-source drugs, or competitive bidding.

"In any state that provides open access, manufacturers would make payments equal to one-third of the Medicaid Discount Payment for the period from enactment to October 1, 1991, and two-thirds of the Medicaid Discount Payment for the period from October 1, 1991 to October 1, 1992."

Upjohn

"The Upjohn proposal is for a formula offering 75-cents claims processing and 3% of the total prescription cost [to] provide a weighted prescription rebate. Total prescription price provides a simple and convenient anchor on which to calculate future rebates and includes increases in pharmacist reimbursement.

"Advantages of the weighted prescription rebate formula are:

"0n average, the rebate per prescription would range from less than $1.00 to $2.48 per supplier with the major research pharmaceutical manufacturers contributing larger rebates.

"Administrative simplicity.

"Rebate calculations are possible from Medicaid Management Information System (MMIS) data.

"Total rebate savings should exceed $300 million, assuming 220 to 250 million Medicaid prescriptions at an average of $1.30 to $1.40 per prescription."

Several other PMA member companies have endorsed one or more of these four proposals. Perhaps more important, more than a dozen PMA companies are now reported to be negotiating discounts and rebates with Medicaid officials. These companies represent slightly more than half of the Medicaid single-source drug market. Forty-two states are involved in these negotiations; they a represent more than 90% of the total Medicaid drug market.

A hallmark of the negotiations now being undertaken in the states is that, in return for discounts or rebates, states are providing Medicaid patients greater access to new innovative prescription drugs. That is an overarching objective of virtually all of the organizations that have joined together in the coalition to oppose S. 2605 or the 0MB proposal or both. Any Federal legislation which could impede the current trend in the states would be counterproductive to better, more cost-effective health care in the Medicaid program and should not be enacted.

H.R. 5589/S. 3029

This past Wednesday Congressmen Wyden and Cooper and Senator Pryor introduced legislation (H.R. 5589 and S. 3029) to require rebates from drug manufacturers whose products are prescribed in the Medicaid program. In his introductory remarks, Senator Pryor made clear that S. 3029 is not a substitute for S. 2605, which he is still advocating. Each of the bills is quite complex, and my comments at this hearing are based on our initial impressions. Nevertheless, I would like to make several points on the bills.

- Statements regarding H.R. 5589 and S. 3029 could lead to an interpretation that a drug would be automatically available to patients in the Medicaid a program if the manufacturer provided a rebate. A reading of the bills themselves, however, indicates that this is not the case. Even if the manufacturer provided a rebate, states could still subject any drug to a prior-approval system. In an attempt to simplify the current unsatisfactory prior-approval systems, the bills would provide for an immediate telephonic response to a request by a doctor for prior approval. The bills do not, however, provide any criteria for prior approval or disapproval, or provide an appeal procedure if the doctor is overruled. By requiring prior approval for some drugs and not others, this provision would permit a *de facto* restrictive formulary even though all manufacturers would be required to provide a rebate. All of this is in sharp contrast to what is happening in the states now in negotiations for discounts and rebates in the Medicaid program; states are providing automatic access to new innovative drugs in return for discounts or rebates.
- H.R. 5589 and S. 3029 are inherently unfair. Their economic impact would vary widely from company to company. The bills, for example, would index a "best price" given to the Department of Veterans Affairs in order to calculate a rebate in the Medicaid program. Many of our companies are reported as giving deep discounts to the DVA, a practice that for some goes back to World War II. Those companies would be hit hardest under the bills. Penalizing a company for having a practice of giving a deep discount to the Department of Veterans Affairs—a practice which I would submit is not reprehensible—is not sound public policy.
- The idea of price controls is inimical to this country's free-market economy. Price controls are totally unreasonable in the absence of controls over a manufacturer's cost of doing business, including wages, energy, transportation, etc. A quintessential feature of recent worldwide developments is that free-market forces serve society far better than centrally planned and administered controls.
- A provision of S. 3029 [Section 1927(f)(3)] seems to be punitive in nature. It requires that if a generic copy of a drug may be dispensed under state law, no payment for the innovator's drug may be made *even* if it is less expensive to the program than the generic. The thrust of both bills in the multisource arena is discriminatory. Companies doing multisource drug—are treated very differently depending on whether they are an originator or a copier, with the originator being greatly disadvantaged. This raises fundamental issues of fairness and serious constitutional questions.
- There is no justification for the provisions of S. 3029 to take money in the form of rebates from manufacturers in order to pay a portion to major chain stores, supermarkets and large mail-order houses, among others. That may be good politics; it is not sound public policy and does, nothing for the Medicaid program.

Mr. Chairman, there are many other aspects of H.R. 5589 and S. 3029 which I know PMA will want to comment on. Given the short time we have had to analyze the bills, I wanted to highlight our most serious initial concerns. Given the keen interest of the Committee on Finance in America's competitiveness, I would hope that the Committee will give serious consideration to the inevitable effects enactment of these bills would have on the very beneficial and internationally competitive research-based pharmaceutical industry.

Mr. Chairman, that concludes my prepared statement. My colleagues and I would be pleased to respond to any questions you and the Subcommittee may have.

Pharmaceutical Manufacturers Association

Attachment 1 to the Statement
Of Gerald J. Mossinghoff

Medicines in Medicaid: Cost-Effective Health Care for America's Poor

Pharmaceutical Innovation: The Key to Medicaid Cost-Effectiveness

Prescription drugs play a key role in the success of Medicaid, a program which provides health care to the nation's poorest patients.

Drugs save lives and extend life expectancy. Equally important, drugs are among the most cost-effective medical technologies, with only about a nickel of every U.S. health care dollar being spent on outpatient prescription drugs. Today's new medicines, in fact, help to restrain escalating health care costs by reducing the need for expensive surgeries, physician visits and hospitalization.

Medicaid patients should have unrestricted access to all drugs approved by the Food and Drug Administration and prescribed by their physicians. Those medications, after all, contribute to not only the health of the patients, but also to the health of the Medicaid program itself.

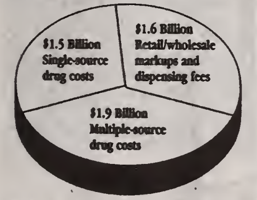
The Role of Prescription Drugs

Medicaid services in fiscal 1988 cost $48.7 billion. Prescription drugs accounted for only $3.3 billion, or 6.7 percent of total spending. On average, the drug cost was $215 for each program recipient.

The prescription drug cost percentage has remained relatively steady in recent years, with

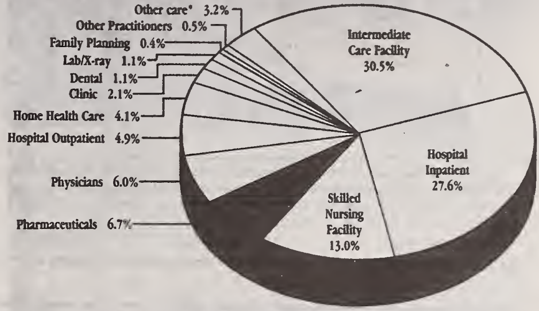
continued on page 2

Medicaid Prescription Drug Expenditures



Projected FY 1991 Medicaid Prescription Drug Expenditures = $5 Billion

Medicaid Spending by Types of Service, 1988



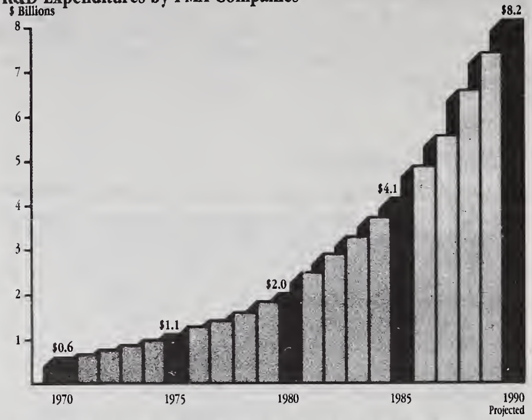
*Other care includes early and periodic screening, rural health clinic services, and miscellaneous other care.

Source: "Pharmaceutical Benefits Under State Medical Assistance Programs," September 1989, National Pharmaceutical Council.

Prescription Drugs and Medicaid: Key Statistics

- Pharmaceuticals account for about 6.7 percent of the total Medicaid budget (includes pharmacists' fees and coverage in most states of some over-the-counter products).
- Single-source or patented drugs amount to only $1.5 billion of the estimated $5 billion cost of Medicaid prescription drug coverage. The sum is less than multiple-source drugs ($1.9 billion) and pharmacy mark-ups and dispensing fees ($1.6 billion).
- In 1989, 16 million people—two out of every three Medicaid recipients—received prescribed drugs under Medicaid.
- The average expenditure per recipient for drugs in 1988 was $215, and the average price per prescription was less than $15.
- About 75 percent of prescription drug payments are for the aged, blind and disabled, and 10 percent are for children.
- Although it is an optional service, every state program has chosen to provide prescription drugs to Medicaid recipients. The programs vary state-to-state. In 19 states, the prescription drug programs include reimbursement restrictions.
- States determine the basic amount to be spent on prescribed drugs. The federal government matches that according to a formula.
- In 1988, Indiana spent more on drugs per Medicaid recipient than any other state, followed by Nebraska, New Hampshire and Georgia. West Virginia spent the least per recipient, followed by Kentucky, California and Mississippi.
- Ninety percent or more of U.S. pharmacies provide drugs to Medicaid recipients. Medicaid is a vendor payment program and pharmacies are paid on a retrospective, fee-for-service basis. Vendor payments for drugs were $3.3 billion in 1988.

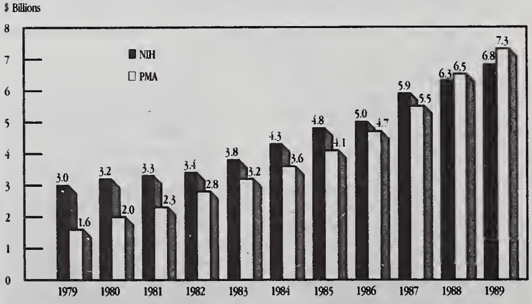
R&D Expenditures by PMA Companies



The best estimates show that research-based pharmaceutical companies will spend about $8.2 billion on research and development in 1990. R&D expenditures have quadrupled in the past decade, and there is no end in sight to the dramatic increases in research spending. PMA companies, in fact, could end up committing more than $130 billion to research and development through the 1990s.

Source: PMA Annual Survey

R&D Expenditures by NIH and PMA Members



In 1989, for the second year in a row, PMA company investment in pharmaceutical research and development surpassed total funding by the National Institutes of Health for biomedical research.

Source: National Institutes of Health and PMA Annual Survey

continued from page 1

only a slight increase in the average expenditure for pharmaceuticals per patient.

Pharmaceutical Innovation and Research

Having already virtually eliminated such diseases as diphtheria and polio, researchers have turned their sights onto medicines for AIDS, cancer, cardiovascular disease, Alzheimer's and other major ailments. As we enter the 21st Century, research-based pharmaceutical companies are on the brink of yet another surge of innovation.

The success of drug companies is especially impressive when the risk and expense of research are considered. The odds are 4,000 to one against market approval, and discarded experiments, or "dry holes," have contributed to the already high cost of research and development.

R&D expenditures quadrupled in the 1980s from $2 billion in 1980 to an estimated $8.2 billion in 1990. It now costs an average of $231 million to develop a single drug.

America's research-based pharmaceutical companies spent more than the National Institutes of Health on biomedical research for the first time in 1988, and then repeated the accomplishment in 1989.

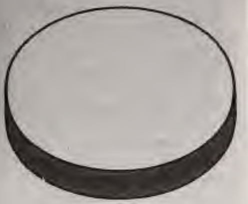
Prices and Cost-Effectiveness

Given the many pressures on prescription drug prices today, pharmaceutical costs are surprisingly equitable. Pharmaceutical prices have increased at a rate only slightly higher than the overall Consumer Price Index.

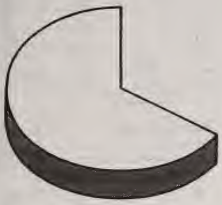
And drugs are cost-effective. They, in fact, are a cost-containment tool when they can be used effectively as alternatives to more expensive surgeries and hospitalizations. Studies and today's scientific literature provide numerous examples of the cost-effectiveness of new medicines.

Market Effects of 1984 Law

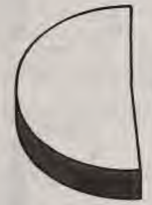
Average Market Share of Pioneer Drugs



100%
At Patent Expiration



65%
1 Year Later

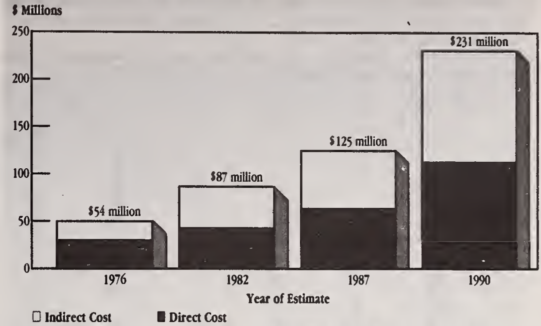


51%
2 Years Later

The use of generic copies of brand-name drugs has been the central cost-control strategy of the federal government. Congress enacted legislation in 1984 making it easier for generics to gain access to the market. The impact on the pharmaceutical industry has been enormous.

Source: H. Grabowski, Ph.D., Unpublished

Cost of Developing a New Drug

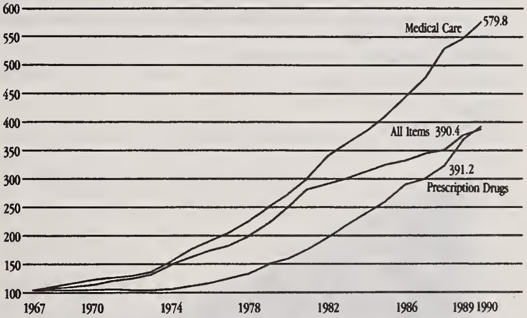


The latest cost estimate for developing a new drug is $231 million, which is more than four times higher than the 1976 estimate of $54 million.

Source: 1976: Ronald Hansen, University of Rochester *1987: Stephen N. Wiggins, Texas A&M University*
1982: Ronald Hansen, University of Rochester, adjusted by PMA for inflation *1990: Joseph DiMasi, Tufts University*

Rx Drug Prices Compared With Other Indices

Consumer Price Indexes 1967–1990



Prescription drug prices have increased at a rate only slightly higher than the overall Consumer Price Index since the index was set at 100 in 1967. Based on the 1967 benchmark, drug prices today are about two-thirds the overall price index for medical care.

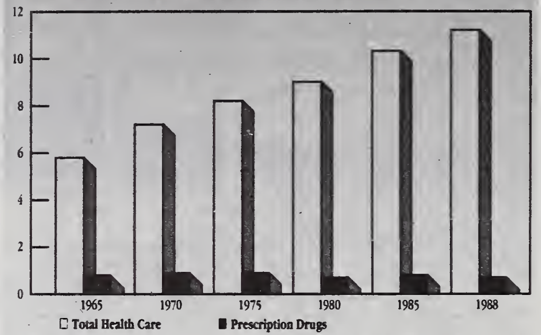
Source: Bureau of Labor Statistics

Drugs as Percent of National Health Expenditures on the Decline

Of every dollar spent on health care, less than seven cents is spent on drugs and sundries. That figure has declined—down from 16.2 cents in 1960—despite the fact that drugs have displaced other more expensive forms of therapy.

While the overall cost of medical care has been an increasing share of Gross National Product (GNP), prescription drugs have been less than one percent of GNP for the past 25 years.

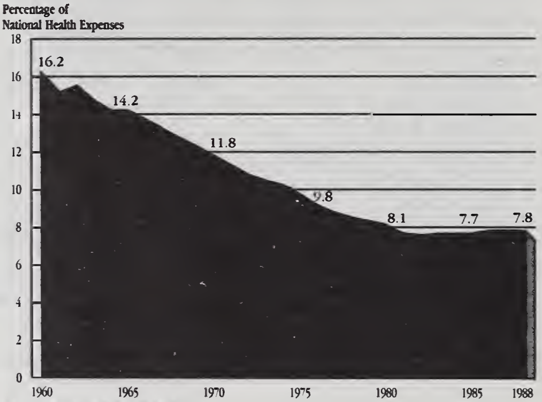
U.S. Health Care Expenditures as a Percent of GNP



Total spending for prescription drugs has stayed under one percent of the Gross National Product (GNP) since 1965, while the percent spent for total health costs has nearly doubled.

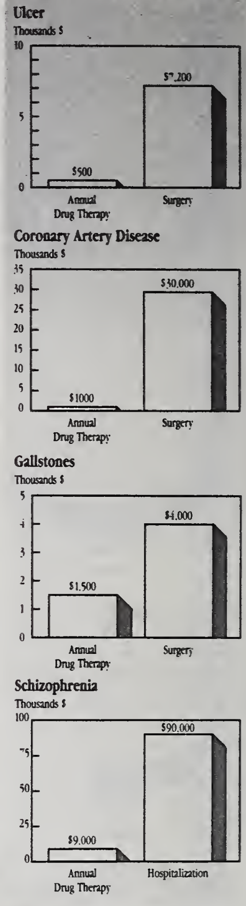
Source: Health Care Financing Administration

Drugs as a Percentage of National Health Care Expenditures (Selected Calendar Years)



Source: Health Care Financing Administration

Treatment Cost Comparison



Pharmaceutical Manufacturers Association

1100 15th Street, NW, Washington, DC 20005

Attachment 2 to the Statement
Of Gerald J. Mossinghoff

OPPOSITION TO S.2605
THE PHARMACEUTICAL ACCESS AND PRUDENT PURCHASING ACT OF 1990

Organizations

American Academy of Allergy and Immunology
American Lung Association of Montana
Arkansas Academy of Family Physicians, Inc.
Chemical Industry Council of New Jersey
Detroit Black Nurses Association
Epilepsy Association of Central Ohio
Epilepsy Federation, St. Louis Region
Epilepsy Foundation of Colorado
Epilepsy Foundation of Long Island
Epilepsy Foundation of Philadelphia
Epilepsy League of Lake Superior
High Plains Epilepsy Association
Huntington's Disease Society of America
Medical Society of Delaware
Mexican-American Political Association
Midwestern Congress of Dermatological Societies
Minnesota Chamber of Commerce
Montana Osteopathy Association
National Multiple Sclerosis Society, Michigan Chapter
National Urban League
Texas Osteopathic Medical Association
United States Hispanic Chamber of Commerce

Members of Congress

Honorable Mike Parker, Mississippi, 4th District

Organizations of State Legislators

The Black Elected Democrats of Ohio
Illinois Legislative Black Caucus
Michigan Legislative Black Caucus
Pennsylvania Legislative Black Caucus

State Legislators

Arizona

State Representative Bart Baker, Chairman, Health Committee

Georgia

State Representative E. M. (Buddy) Childers, Chairman,
  Health and Ecology Committee
State Representative Grace W. Davis
State Representative J. E. (Billy) McKinney
State Representative Tom Wilder

Illinois

State Representative Anthony L. Young, Assistant Majority Leader

Iowa

State Senator Calvin O. Hultman, Minority Leader

Louisiana

State Representative Alphonse Jackson, Jr. Chairman, Health and Welfare Committee

Michigan

State Representative Michael J. Bennane, Chairman, Public Health Committee
Speaker Lewis N. Dodak, House of Representatives

Minnesota

State Senator Linda Berglin, Chair, Health and Human Services Committee
State Representative Brad Stanius
State Senator Donald A. Storm, Assistant Minority Leader

Montana

State Representative Fred Thomas

New Mexico

Speaker Raymond G. Sanchez, House of Representatives

Ohio

Senate President Stanley J. Aronoff
State Senator Grace L. Drake, Chairman, Health and Human Services Committee
State Representative Marc D. Guthrie, Assistant Minority Whip
State Senator David L. Hobson
State Senator Charles F. Horn, Chariman, Economic Development, Science and Technology
State Representative Paul H. Jones, Chairman, Health and Retirement Committee

Rhode Island

State Representative Bradford Gorham, House Minority Leader

South Dakota

State Senator Randy Austad

Tennessee

State Representative Shelby A. Rhinehart, Chairman, Fiscal Review Committee

Texas

State Representative Eddie Cavazos
Speaker Gibson D. (Gib) Lewis, House of Representatives
State Representative Nancy McDonald

Attachment 3 to the Statement
Of Gerald J. Mossinghoff

OPPOSITION TO S.2605 AND OMB PROPOSAL

Organizations

American College of Cardiology/American Heart Association
American Diabetes Association, Arizona Affiliate, Inc.
American Legislative Exchange Council
Arthritis Foundation
Cystic Fibrosis Foundation
Industrial Biotechnology Association
Maine Medical Association
National Black Caucus of State Legislators
National Black Nurses' Association
National Coalition of Hispanic Health and Human Services Organizations
Opportunities Industrialization Centers
Oregon State Council of Senior Citizens
Pharmaceutical Manufacturers Association

State Legislators

Arizona

Senate President Robert B. Usdane

Oregon

State Representative Rick Kotulski, Chairman, Human Resources Committee

South Carolina

Speaker Pro Tempore John I. Rogers, III, House of Representatives

Tennessee

State Senator John N. Ford, Chairman, General Welfare, Health and Human Resources Committee

Utah

Senate President Arnold Christensen

[Attachment 4 to the Statement of Gerald J. Mossinghoff]

MEMORANDUM FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

RE: CONSTITUTIONALITY OF THE PROPOSED PHARMACEUTICAL ACCESS AND PRUDENT PURCHASING ACT OF 1990

In this memorandum, we consider the constitutionality of Senator David Pryor's proposed Pharmaceutical Access and Prudent Purchasing Act of 1990 (the "Act"), S. 2605. The purpose of the proposed Act is to require the State Medicaid agencies to follow a purchasing procedure designed to obtain rebates from the pharmaceutical manufacturers on drugs previously sold to pharmacies and dispensed by them under the States' Medicaid programs. These requirements would be contained in a new Section 1927 of the Social Security Act.

An essential element of this proposed legislation would require the Secretary of Health and Human Services ("the Secretary") to "contract with a non-governmental entity to establish a National Pharmacy and Therapeutics Committee." Proposed new §1927(b)(1). The Committee's function would be to review and evaluate scientific information relating to outpatient drugs approved for marketing in the United States, *id.* at (b)(3), to group each drug "into one or more drug use classes, based upon its medically accepted indications," *id.* at §(b)(3)(i), and to "identify indications for which two or more covered outpatient drugs are therapeutic alternates and list these drugs in groups of therapeutic alternates within each drug use class," *id.* at §(b)(3)(iii). The State Medicaid agencies would then be required to negotiate with the manufacturers of these products for rebates on products dispensed to Medicaid beneficiaries. *Id.* at §(c). Within each product category Medicaid, reimbursement to pharmacies would be restricted to the product of the particular manufacturer that offers a rebate resulting in the lowest net cost. *Id.* at §(a)(9).

Based on the analysis that follows, we conclude that a court should hold the provisions of the Act relating to the National P&T Committee to be unconstitutional for two reasons: (1) because the establishment of such a Committee would unconstitutionally delegate an important governmental function to a private body, and (2) because the essentially unreviewable discretion granted to the Committee would violate the traditional norms associated with legislative due process.

A. THE PROPOSED STATUTE

As noted above, the proposed statute would authorize the creation of a National Pharmacy and Therapeutics (P&T) Committee, whose function it would be to group prescription drug products into therapeutic classes, and then, within each class, to identify those particular products that the Committee deems equally safe and effective for each medically accepted purpose.

The National P&T Committee would be comprised of "medical aid scientific professionals," Act at §(b)(2)(A),[1] "with recognized knowledge of appropriate utilization of prescription and nonprescription drug therapies, and of the relative safety and efficacy of covered outpatient drug products." *Id.* The Committee would be a "non-governmental entity" with which the Secretary of Health & Human Services ("HHS") would "contract" for the performance of its functions. *Id.* at §(b)(1).[2] The

---

[1] "In addition to physicians, who shall form a majority of its membership," the Committee is to "have at least one member from each of the following categories of health care professionals": (a) dentists, (b) nurses, (c) pharmacists, (d) experts in geriatric problems associated with drug therapies, (e) experts in pediatric problems associated with drug therapies, (f) experts in psychiatric or neurological problems associated with drug therapies, (g) experts in clinical pharmacology, (h) experts in pharmacoepidemiology, (i) experts in comparative clinical trials of drugs, (j) experts in obstetric problems associated with drug therapies, and (k) other categories of health care professionals that the Secretary or Committee determines should be represented. *Id.* at §(b)(2)(A).

[2] Given the language of the proposed statute, we assume that the constitutionality of the Act would not be defended on the grounds that the members of the National P&T Committee are government officials, rather than private parties. However, even if the National P&T Committee members were to be recharacterized as government officials, it is clear that the legislation would violate the Appointments Clause of the Constitution.

The Appointments Clause requires that officers of the United States, i.e., "[a]ny appointee exercising significant authority pursuant to the laws of the United States," *Buckley* v. *Valeo,* 424 U.S. 1, 126 (1976), must be appointed either by "the President alone, by the heads of departments, or by the Judiciary." *Id.* at 132. Because the members of the National P&T Committee are to be nominated and elected by members of the medical and scientific community, it is beyond doubt that the Appointments Clause would not be satisfied. *See also Olympic Federal*

Continued

Act provides that, "[w]ithin thirty days of receiving written notice of a determination by the [Committee], the Secretary shall cause the determination to be published for public comment, for not less than sixty days. The Committee shall make appropriate revisions upon consideration of the comments and then transmit a final version to the Secretary . . ." *Id.* at §(b)(6)(A). The Act further provides that the "Secretary shall make no changes with respect to the substance of any determinations made by the (Committee) but may comment during the public comment period, and may request reconsideration by the Committee of any determination." *Id.* at §(b)(6)(B).

The National P&T Committee's listings would be used by multiple-state Medicaid prescription drug buying groups in negotiating prescription drug rebates with the manufacturers of those products. *Id.* at §(c)(2). The buying group would use the results of these negotiations to identify a "preferred" product in each category—*i.e.,* a drug available at a price which is determined to offer "superior economic advantages relative to other drugs in the same drug class." *Id.* at §(a)(9). Pharmacists would receive Medicaid reimbursement only for these preferred products. *Id.* at (d)(2). Where a physician has prescribed a non-preferred product for an indication for which a preferred product has been determined to be a "therapeutic alternate" (and the physician has not written a restrictive prescription), pharmacists would be authorized to substitute the preferred product. *Id.*

In our view, a court should rule that the delegation made by the proposed statute is unconstitutional. The entire statutory scheme would turn on a delegation to the National P&T Committee of the power to make unreviewable discretionary governmental decisions. Indeed, these decisions as to which drugs are therapeutic equivalents are the only decisions contemplated by the statute that require the exercise of substantial judgment and discretion.[3]

In making its decisions, the P&T Committee is to "continuously review and evaluate existing and newly available scientific and medical information pertaining to the relative safety and efficacy, and the comparability, of covered outpatient drugs approved for marketing in the United States." *Id.* at §(b)(3).[4] It is well known, however, that such determinations of therapeutic equivalency are subject to wide differences of opinion among professional experts. Physicians, clinical pharmacologists, pharmacists, pharmaceutical manufacturers and others often disagree about the extent to which such determinations can accurately be made. These disagreements exist not only across professional lines, but also among practitioners within each of the professions.

While there would be no constitutional objection to the legislative delegation of such subjective judgments to an officer of the executive branch (subject to the degree of judicial review required by due process), there are major constitutional flaws in delegating' this task to private citizens—no matter how well qualified—without any effective review by an executive branch officer or any opportunity for judicial review.

The proposed statute removes these important determinations from virtually all of the government channels through which such decisions usually are made. It not only bypasses entirely the Food and Drug Administration—the government body which has heretofore been vested with the responsibility for similar determinations—but denies even the Secretary of HHS the power to alter the Committee's decisions. And though the statute provides for a period of public comment, it does not require the Committee, after consideration of these comments, to make any statement of the basis and purpose of its determinations. *Cf.* 5 U.S.C. §553(c) (rule making procedures under the Administrative Procedure Act). Finally, the statute allows the Committee to make its decisions without any opportunity for judicial review.

As we show below, our system of government requires that decisions of such public importance be made by the legislature or delegated to an officer of the execu-

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Savings and Loan Assoc. v. *Office of Thrift Supervision,* No. 90-0482 slip op. at 23 (D.D.C. March 21, 1990) (appointment of director of Office of Thrift Supervision was unconstitutional because made by operation of congressional statute rather than by an act of the President, the head of any department, or the judiciary).

[3] The Act would give the Secretary, who would be entitled only to submit comments and request reconsideration of Committee determinations, little more power to affect those determinations than any member of the interested public.

[4] In doing so, the Committee is supposed to "take into consideration, for each drug, mechanisms of action, therapeutic indication, and such other differences among the drugs as the method by which they are metabolized, dosage ranges, known side effects, allergies, toxicities (frequency and type, prevention, risks and benefits), and other special precautions (contraindications and drug-to-drug interactions)." *Id.*

tive branch, subject to appropriate judicial review. The proposed statute does just the opposite of that.

I. THE PROPOSED LEGISLATION WOULD UNCONSTITUTIONALLY DELEGATE AN IMPORTANT GOVERNMENTAL FUNCTION TO A PRIVATE BODY

Although it has been more than fifty years since the Supreme Court has invalidated a congressional delegation of lawmaking authority to a governmental administrative agency or officer of the executive branch,[5] it seems clear that the Court would still invalidate a delegation of such authority to a private body whose decisions were not subject to review by a government officer. While the courts have long recognized the important role that private groups can and ought, to play in formulating national and state policy, particularly when specialized scientific or technical judgments are involved.[6] the role of private parties has always been seen as an "advisory" rather than a law-making one.[7]

In the leading case on point, *Carter* v. *Carter Coal Co.,* 298 U.S. 238 (1936), the Court struck down the Bituminous Coal Conservation act of 1935, which directed private district boards, elected by coal companies, to set minimum prices and fix hours and wages. The Court wrote that legislative delegation to private persons is "legislative delegation in its most obnoxious form." 298 U.S. at 311. The Court went on to say:

> The difference between producing coal and regulating its production is, of course, fundamental. The former is a private activity; the latter is necessarily a governmental function. . . . And a statute which attempts to confer such power undertakes an intolerable and unconstitutional interference with personal liberty and private property.
>
> *Id.* at 311. [8]

While the *Schechter* doctrine may have become moribund in cases involving delegation of law-making power to governmental agencies, [9] no subsequent case has weakened Carter Coal's strictures against delegating such power to purely private entities.

For example, *Opp Cotton Mills Inc.* v. *Administrator,* 312 U.S. 126 (1941), involved a challenge to the Fair Labor Standards Act. The particular program involved called for the setting of minimum wages for particular industries by an officer of the United States "in collaboration with an industry committee" composed of private individuals. *Id.* at 134. Although it was the committee that investigated industry conditions and determined the appropriate wage to be fixed, the Court ruled that sufficient governmental control was maintained by the Act's requirement that a government officer conduct a hearing arid make the actual order: "Thus, under the provisions of [the Act), no wage is fixed which is not recommended by the committee, and not then without appropriate hearing, findings and order by the Administrator." *Id.* at 147.

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[5] *See A.L.A. Schechter Poultry Corp.* v. *United States,* 295 U.S. 495 (1935) (invalidating §3 of the National Industrial Recovery Act ("NIRA"), which empowered trade associations to create codes of fair competition approved by the President); *Panama Refining Co.* v. *Ryan,* 293 U.S. 388 (1935) (invalidating §9(c) of the NIRA, which directed the President to prohibit transportation of petroleum in excess of the amount permitted by state law).

[6] As Justice Cardozo put it in his concurrence in *Schechter Poultry,* the "industries of the country are too many and diverse to make it possible for Congress . . . to legislate directly with adequate appreciation of the varying conditions. . . . When the task that is set before one is that of cleaning house, it is prudent as well as usual to take counsel of the dwellers." 295 U.S. at 552 (Cardozo, J., concurring).

[7] In *Schechter,* Cardozo emphasized that the role of such "dwellers" is to be "strictly [an] advisory" one; it is the "*imprimatur* of the [elected official] that begets the quality of law." *Id.*

[8] *See also* Freedman, *Delegation of Power and Institutional Competence,* 243 U. Chi. L. Rev. 307, 332–33 (1976) [hereinafter *Institutional Comnetence*]:

> [T]he Court's language in *Carter* suggests its recurrent concern with the question of whether private persons, even though they have been selected by Congress, can be relied upon to exercise the sovereign power of the nation with the disinterestedness sufficient to assure that the interests of all of those subject to regulation will receive fair consideration—consideration of at least the quality and fairness they would receive in a politically accountable legislative forum.

Thus, delegation to a private rulemaking body poses a particularly serious form of the fear that any form of legislative delegation provokes—namely, that it allows "controversial choices [to be] made without votes being taken and responsibility being publicly assumed by members of Congress." Schoenbrod, *The Delegation Doctrine: Could the Court Give it Substance?,* 83 Mich. L. Rev. 1223, 1244 (1985).

[9] As the Court noted in *Synar* v. *United States,* 626 F.Supp. 1374, 1384 (D.D.C.), *aff'd sub nom. Bowsher* v. *Synar,* 478 U.S. 730 (1.986):

> [The Court's] attempts at narrowing [the holdings of *Schecter Poultry* and *Panama Refining*], and the Supreme Court's failure to use the delegation doctrine to strike down a statute in fifty years, have led some to conclude that the delegation doctrine is dead, or at least "moribund." The Court has continued to use the doctrine, however, in an interpretive mode, finding that statutory texts conferring powers on the Executive should be construed narrowly where broader construction might represent an unconstitutional delegation. Such cases indicate that while the delegation doctrine may be moribund, it has not yet been officially interred by the Court.
>
> (citations omitted).

An analogous principle has been expressed in cases involving challenges to the Maloney Act, 15 U.S.C. §780–3(b)(6), which provides that the National Association of Securities Dealers ("NASD"), a "voluntary association" consisting of private securities brokers and dealers, shall promulgate rules to protect investors and the public. In *First Jersey Securities, Inc.* v. *Bergen,* 605 F.2d 690 (3d Cir. 1979), *cert. denied,* 444 U.S. 1074 (1980), for example, it was argued that the Maloney Act is an unconstitutional delegation of legislative power to a private institution. The Third Circuit rejected this argument on the grounds that, under the statute, the SEC retains the power to "approve or disapprove the Association's rules." 605 F.2d at 697. *See also R.H. Johnson & Co.* v. *Securities and Exchange Commission,* 198 F.2d 690, 695 (2d Cir.) (Frank, J.) (Act did not unconstitutionally delegate power to NASD where SEC retained power "to approve or disapprove of the association's Rules"), *cert. denied,* 344 U.S. 855 (1952).

The courts have also approved of statutes which have incorporated by reference, after review by a governmental body, factual findings or guidelines which were developed by private groups for prior and independent reasons. For example, regulations setting forth a "national consensus standard" promulgated pursuant to the Occupational Safety and Health Act ("OSHA"), 29 U.S.C. §660(a), are derived in part from standards adopted by the American National Standards Institute ("ANSI"), a private organization. In *Noblecraft Industries, Inc.* v. *Secretarv of Labor,* 614 F.2d 199 (9th Cir. 1980), these regulations were challenged on the grounds that Congress had improperly delegated legislative and administrative duties to a private group. The court rejected this contention on the grounds that "OSHA in practice did not surrender to ANSI all its standard-making function. As was the case here, it selected among the ANSI standards with apparent discrimination." 614 F.2d at 203.

A similar conclusion was reached by a Federal court considering a challenge to a Kansas statute under the Kansas State Constitution. Pursuant to the Kansas Boiler Safety Act, Kan. Stat. Ann. §44–913 et. seq. (1986), the Kansas Department of Resources incorporates by reference a safety code developed by the National Board of Boiler and Pressure Vessel Inspectors, a private organization. The statute was upheld in *North American Safety Valve Industries, Inc.* v. *Wolgast,* 672 F. Supp. 488 (D. Kan. 1987). Looking to Federal delegation doctrine and separation of powers law as a guide in interpreting the Kansas Constitution, the district court concluded that the statute was not unconstitutional precisely because the rules promulgated by the National Board could be adopted as "Kansas law only *after* the agency submits the amendment to the secretary of administration and the attorney general [for approval], *after* notice and a public hearing, and *after* the legislature examines the amendment." 672 F. Supp. at 493.[10]

Unlike the Federal courts, the state courts have had occasion to consider statutes which, like the proposed Pryor bill, make no provision for governmental review of rules made by private groups. Not surprisingly, most of these statutory schemes have been invalidated. *See, e.g., Group Health, Ins. of New Jersey* v. *Howell,* 40 N.J. 436, 447, 193 A.2d 103, 109 (1963), *supplemented,* 43 N.J. 104, 202 A.2d 689 (1964) (statute providing that no corporation can secure certificate of authority to transact business as a medical science corporation without first obtaining approval of corporation's prospective trustees by State Medical Society—a private group—is unconstitutional delegation of Legislature's licensing power); *State* v. *Allstate Ins. Co.,* 231 Mis. 869, 97 So. 2d 372 (1957) (statute may not validly authorize majority of insurance companies authorized to do business in state to fix the rates of agents' commissions); *City of Alexandria* v. *Alexandria Fire Fighters Ass'n,* 220 La. 754, 759, 57 So.

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[10] *See also State* v. *Wakeen,* 263 Wis. 401, 57 N.W.2d 364, 369 (1953) (statute prohibiting sale of drugs except by registered pharmacists and incorporating definition of "drug" recognized in the official United States Pharmacopoeia, official Homeopathic; Pharmacopoeia of the United States, or official National Formulary, did not violate Wisconsin Constitution's nondelegation doctrine because the "publications referred to in the statute are! not published in response to any delegation of power, legislative or otherwise, by the statute. . . . These books were published before the enactment of our statute and not in response to it").

2d 673, 675 (1952) (statute fixing maximum hours at 72 per week but making maximum 60 in any city in which a majority of firemen so vote held unconstitutional because legislative function delegated to private group); *Fink* v. *Cole,* 302 N.Y. 216, 225, 97 N.E. 2d 873, 876 (1951) (delegating power to license horse owners, trainers and jockeys held to be "such an abdication as to be patently an unconstitutional relinquishment of legislative power"); *Hollingsworth* v. *State Board of Barber Examiners,* 217 Ind. 373, 28 N.E.2d 64 (1940) (statute permitting 80% of licensed barbers to fix prices and opening and closing hours held unconstitutional); *see also* K. Davis, 1 *Administrative Law Treatise* (1958 ed.) at §2.14; Abramson, *A Fifth Branch of Government: The Private Regulators and Their Constitutionality,* 16 Hastings Const. L.Q. 165 (1989); Liebmann, *Delegation to Private Parties in American Constitutional Law,* 50 Ind. L.J. 650 (1975); Jaffe, *Law Making by Private Groups,* 51 Harv. L. Rein. 201 (1937) (all reviewing Federal and state court decisions regarding delegation to private groups).

The constitutionality of delegating governmental authority to a group composed in part of private individuals was considered most recently in *Melcher* v. *FOMC,* 644 F. Supp. 510 (D.D.C. 1986), *aff'd on other grounds,* 836 F.2d 561 (D.C. Cir. 1987), *cert. denied,* 108 S. Ct. 2034 (1988). The case concerned a challenge to the constitutionality of the Federal Reserve Board's Federal Open Market Committee ("FOMC"). A minority of FOMC's membership is chosen by the boards of directors of the several Federal Reserve Banks. The boards consist of private individuals elected by the private banks which own the voting stock of the Federal Reserve Banks. The court considered whether the "type of decision making in which (the FOMC] engages must constitutionally be performed by government officials, or whether, to the contrary, it may validly be performed, at least in part, by otherwise private individuals." 644 F. Supp. at 520. The court, apparently oblivious to the many authorities relevant to the issue, found this to be a question of "first impression." *Id.* at 520.

The court reviewed the history of the regulation of the nation's monetary system and found a "subtle and conscious balance of public and private elements." *Id.* at 521. In light of this history, it concluded that "at least some" of the Article I, section 8 power to "coin money" and to "regulate the value thereof" (which the court assumed to be the basis for the open market trading activities engaged in by the FOMC) may constitutionally be delegated to private persons.

Several factors militate against placing too much weight on the result arrived at in *Melcher.* First, the holding of the case is by its own admission a narrow one, and seems to turn on the peculiar historical role that the banking industry has played in its own regulation and the peculiarly private nature of fixing interest rates. The court expressly noted that it was not deciding "which of the powers entrusted to Congress by Article I, section 8 . . . other than those directly" exercised by the FOMC "may be delegated to private individuals." *Id.* at 523. The court also noted that the historical involvement of private interests in the banking industry was significant: "Other responsibilities, unlike the functions at issue here, lack a history of private participation, and that fact may well make a significant difference in terms of any attempted delegation to individuals who are not officers of the government." *Id.* (note omitted).[11]

Second, it is significant that privately appointed individuals make up only a minority of the membership of the FOMC;[12] therefore, unlike a group constituted solely of private members, the FOMC could be "captured" by private interests only in highly unusual circumstances. Third, the case was affirmed on grounds entirely separate from the constitutional principles dealt with here.[13] Fourth, by suggesting that the only alternative to a "partnership" between the public and private spheres is "exclusive[]" execution of the responsibilities in question by "government officials," *see id.* at 523, the opinion ignores the far more common and appropriate subsidiary role that private groups have played as a valued "advisor" to government bodies which ultimately retain control. Finally, as noted, the opinion fails to consider any of the relevant case law on point, including most notably the Supreme Court's opinions in *Carter* and *Schechter Poultry.*[14]

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[11] The history of food and drug regulation in this country is, of course, vastly different from the history of banking regulation. Though the Food and Drug Administration ("FDA") has at times made use of governmental advisory panels, *see Weinberger* v. *Hynson, Westcott & Dunning Inc.,* 412 U.S. 609, 614–15 (1973) (describing process by which FDA used factual findings of the National Academy of Sciences—National Research Council as a basis for promulgating its own regulations), and has more often than not adopted such recommendations, the ultimate regulatory decisions have always remained in FDA hands. Thus, even under the historical approach suggested in *Melcher,* the proposed statute would be unconstitutional.

[12] *See Melcher,* 644 F. Supp. at 512 n. 1 ("the FOMC consists of seven members who hold their offices by virtue of presidential appointments confirmed by the Senate, and five members who are elected by Reserve Bank boards of directors, and who hold their offices subject to the approval of the Board of Governors").

[13] *See Melcher* v. *FOMC,* 836 F.2d 561 (D.C. Cir. 1987) (district court should have exercised its equitable discretion to decline to hear case), *cert. denied,* 108 S. Ct. 2034 (1088).

The role envisioned for the National P&T Committee by the Pryor bill is much more than that of an advisor to—or even a partner of—the Secretary of HHS. Indeed, the Secretary would expressly be barred from making any "changes to the substance of any determination" made by the Committee. In our view, such legislation would comprise an unconstitutional delegation of power.

II. THE PROPOSED STATUTE VIOLATES LEGISLATIVE DUE PROCESS

Closely related to the nondelegation/separation of powers concerns expressed in the previous section is the concern that the proposed statute would violate the norms of legislative due process.[15] In *Carter Coal,* the Court made explicit the connection between the nondelegation doctrine and due process, holding that Congress' delegation of rulemaking authority to private district boards "is so clearly arbitrary, and so clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment, that it is unnecessary to do more than refer to decisions of this court which foreclose the question." 298 U.S. at 311; *See also McGautha* v. *California,* 402 U.S. 183, 272 n. 21 (1971) (Brennan, J., dissenting) ("[a]s applied to the Federal Government, the [delegation] doctrine appears to have roots both in the constitutional requirement of separation of powers and in the Due Process Clause of the Fifth Amendment").

Other courts and commentators have followed suit, suggesting that, even where procedures for notice and comment in administrative rulemaking are not required by statute, the Due Process Clause of the Fifth Amendment nonetheless requires that (at least) certain minimal procedures be observed. *See, e.g., Thomnson v. Washington,* 497 F.2d 626, 634–35 (D.C. Cir. 1973) (Leinenthal, J.):

> While many procedural due process cases involve the judicial process, the principles are fully applicable to any executive or administrative forum entrusted with determinations of significant rights. That gas held as long ago as *Londoner* v. *City of Denver,* [210 U.S. 373] (1908), where the duty of making street improvement assessments and apportioning of taxes was vested in a board of equalization. The Court held that notice and hearing by the board were required before the tax was irrevocably fixed, although "[m]any requirements essential in strictly judicial proceedings may be dispensed with. . . ." [210 U.S. at 386] Application of due process protection to executive and administrative action has followed from recognition of the basic principle that "the constitutional right to be heard is a basic aspect of the duty of government to follow a fair process of decision making." *Fuentes* v. *Shevin,* [407 U.S. at 80.]

The demands of legislative due process are particularly strong in cases where the legislating function is delegated to a non-governmental private entity.[16]

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[14] This point is also made in Note, *The Federal Open Market Committee and the Sharing of Governmental Power with Private Citizens,* 75 Va. L. Rein. Ill, 152–53 (1989) (criticizing the opinion in *Melcher* and concluding that "[i]t is not too much to argue that the sharing of governmental authority with private representatives, particularly those with an interest in that area of regulation, fails the constitutional test. The delegation of policy making power to private citizens blurs the line between what is public and what is private . . . . While the FOMC may need the advice and cooperation of the Reserve Banks in setting open market trading policies, that advice can be obtained, and in fact is already obtained in other areas, from the Federal Advisory Council.")

[15] Legislative due process is also sometimes referred to as "due process of lawmaking." *See Bowsher* v. *Synar,* 478 U.S. 730, 757 n. 23 (1986) (Stevens, J., concurring) ("I have previously' noted my concern about the need for a 'due process of lawmaking . . . . When a legislature's agent is given powers to act without even the formalities of the legislative process, these concerns are especially prominent.") *See also* Abramson, *A Fifth Branch of Government: The Private Regulators and Their Constitutionality,* 16 Hastings Const. L.Q. 165, 208–210 (1989); Lind, *Due Process of Lawmaking,* 55 Neb. L. Rein. 197 (1976).

[16] As Professor Friedman has observed:

> One of the reasons that delegations of legislative power to the President are so often sustained undoubtedly relates to a recognition of his special character as a delegate. He is a public official, sworn to uphold the Constitution and the laws of the United States, constrained to public spiritedness by the nation's traditions and history's certain judgment, and within the reach of a

Continued

The statute proposed by Senator Pryor is no less "obnoxious" than that struck down by the Supreme Court in *Carter.* The statute would provide for the delegation of an important governmental function to an essentially unaccountable private body which would make its decisions guided by few standards, without any obligation to state the basis and purpose of its determinations, without any provision for judicial review, and without giving the Secretary any power to make substantive changes. The bill offends basic notions of legislative due process in the most profound way.

CONCLUSION

We conclude that, on either or both of the grounds set forth above, a court should rule that the Pryor bill's delegation of law-making authority to the National P&T Committee would be unconstitutional.

Prepared Statement of James Parks

Mr. Chairman and committee members, I am Jim Parks, Chief of the Medicaid (Medi-Cal) Drug Discount Program, for the California of Health Services. I am here to make a brief presentation California's recently enacted legislation authorizing a drug discount program and to provide general information about the status of the program.

I would also like to provide some suggestions about what type of Federal legislation would assist state Medicaid agencies achieve their concurrent goals of obtaining discounts from pharmaceutical manufacturers while also assuring Medicaid beneficiaries access to a full range of medically appropriate drug therapies. At the conclusion of my remarks, I will also be available to answer any questions you may have relative to the issue of pharmaceutical drug product discounting.

The Medi-Cal Program pursued the issue of achieving significant discounts from pharmaceutical manufacturers for several reasons:

1. The drug program was one of the fastest growing components of the entire Medi-Cal program.
2. Because of this growth, there was a growing reluctance to add additional drugs to the Medi-Cal Drug Formulary because of the cost implications.
3. The types of discounts available to private health care enterprises and other governmental agencies seem to offer a way for Medi-Cal to be able to afford to add new drug therapies without necessarily increasing the drug program budget.
4. A review of pharmaceutical manufacturer discount practices convinced us there was no legitimate reason why a state Medicaid agency should not be able to obtain a discount if that was explicitly made a requirement for a manufacturer's product being eligible for reimbursement by the program.

The discounts available to some other governmental agencies ranged from a low of 5–6% to as high as over 100% for some single source products. Allow me to give you a couple of examples: Ceslor 250 mg.tablets, used to treat certain types of respiratory infections, are reimbursed by Medi-Cal for $149.00/100 tablets, Los Angeles County and the Veterans Administration pays approximately $55.67 for the same quantity; Tagamet 300 mg. tablets, used for treatment of ulcers, are reimbursed by Medi-Cal for $54.77 for 100 tablets; Los Angeles County pays $38.59 and the Veterans Administration pays $27.65 for the same quantity. Obviously, generically available multi-source products often see even higher discounts made available in an open, competitive environment.

The Department initially proposed drug discount legislation in January, 1989. We were unsuccessful largely because of intensive lobbying by the Pharmaceutical Manufacturers Association and its individual companies, and the absence of active support at any level for the proposal outside the Department itself. However, this year we successfully obtained passage of authorizing legislation.

The major elements of the Medi-Cal Drug Discount Program legislation include:

1. The department's retention of control of a formulary, now referred to as a "list of contract drugs";
2. The continued use of five criteria for the evaluation of drugs for placement on the list of contract drugs—safety, efficacy, essential need, misuse potential and cost;

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number of political and finally electoral processes. Rarely are private partied exercising delegated legislative power circumscribed by such profound imperatives.

Institutional Competence, 43 U. Chi. L. Rein. at 334.

3. Provisions allowing the department to contract for drugs on a bid or nonbid, and the confidentiality of negotiated contracts from disclosure,
4. The ability of the Department to establish an advisory body composed of experts in individual therapeutic categories, to advise the Department of appropriate drug representation within each therapeutic category;
5. A provision for "grandfathering" drugs already on the list of contract drugs, subject to a negotiated contract (price discount);
6. Provisions for handling drug addition requests which were "deemed denied" to enable the Department to dispense with a very lengthy administrative hearing process;
7. A commitment by the Department to enhance the prior approval process for drugs not on the list of contract drugs, including periodic reports to the state legislature on the overall impact of the drug discount program on beneficiaries, providers, and the savings achieved by the program; and
8. A two year sunset on the provisions of the Medi-Cal Drug Discount Program to enable the state legislature to assess the Department's performance in this area.

Indisputably, an important, integral part of our discussion today should include Medi-Cal's use of a drug formulary. Generally, a drug formulary is a list used to identify preferred drugs that are covered under a given health care program. For many years, hospitals, private health care programs, and governmental health agencies out the country have been using drug formulary systems in their administration of pharmaceutical service programs. The purpose of these drug formularies is to improve the quality and control the cost of drug therapy. Since the medical care of patients in any health care organization is often dependent upon the effective use of drugs, the evaluation and selection of specific drugs has become the standard process for providing appropriate and economical drug therapy. The formulary system within hospitals has become so important that such a system is now a requirement or recommendation of Title 22 of the California Code of Regulations, the Code of Federal Regulations, and the Joint Commission on Accreditation of Healthcare Organizations (JACHO.)

As regards the frequently heard allegation that Open Formularies save money, that simply is not the case. I have available and would like to share with you our most recent analysis of this issue. Attached to that is the Department's cost analysis for an Open Formulary in the California Medicaid program.

Perhaps the central fallacy of arguments supporting an Open Formulary is the presumption that all new drugs approved by the FDA equal improvements in health care. First of all, the FDA approves the addition of new drugs to the American market solely on the basis of safety and efficacy. This approval is not contingent upon comparing the new drug that is FDA approval with other drugs of similar therapeutic use. This is why a formulary system is so valuable.

Second, the FDA does classify new drugs according to its chemical type and therapeutic potential. I think it is important to point out that of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, only 12, or 3% of the total were rated type "A", designating these as "Important Therapeutic Gains." Only 44, or 13% were rated type "B", representing "Modest therapeutic Gain." The remainder, 292 or 84% were rated type "C", providing "Little or no therapeutic gain." Within the health care profession, drugs that provide little or no contribution to existing therapies are known as "me-too" drugs. Unfortunately, it is well known that the majority of new drugs are priced significantly higher in most cases than older available medications.

California's formulary is used as the base from which many private health care organizations build their own formularies, and, because of that, pharmaceutical manufacturers have conceded the importance of getting their product listed on it. A number of other states also employ formularies for many of the same reasons. More than any other, it is the formulary that gives private health care organizations the clout to successfully demand discounts from pharmaceutical manufacturers.

Briefly, I would like to share with you the status of California's Medi-Cal Drug Discount Program. As of September 7, 1990, we have reached agreement on contracts with four manufacturers. Two of those, Merck, Sharp, and Dohme, and Glaxo, Inc., have been publicly announced, we expect to announce the other two within the next few days. These four contracts, cumulatively have resulted in the addition of fifteen drugs to the Medi-Cal list of contract drugs (formerly the Medi-Cal Drug Formulary), two of which are 1A drugs, and four of which fill gaps in drug therapeutic categories. The cumulative cost of the addition of all but one of these drugs is approximately $25,300,000; and the cumulative anticipated savings is approximately $26,731,000 for the duration of the contracts. It is worth noting that the one drug excluded from the above information is the first drug we have added in a new category of cholesterol lowering drugs. The anticipated cost of that one drug, Mevacor, is approximately $20,315,000 over the life of the contract.

As stated earlier, we have concluded contract discussions with another two companies with announcements expected shortly, and we have already scheduled five additional contract negotiations within the next few weeks. All but one of our contracts have resulted in net savings to the California Medicaid program over the term of the contracts.

Our contracts, by state law and manufacturer requests, are confidential in nature, so I cannot reveal the specifics of any individual contracts, however, I can share some general information. Discounts vary from being very low to offers of "best price" on individual drugs; contract length averages in the 3 to 5 year range, and all contracts have resulted in the addition of at least some drugs to the list of contract drugs. All contracts have provisions which assure that discounts do not shrink through the normal process of price increases; and finally, all discounts are achieved through a rebate mechanism that does not require any of direct drug purchase and/or redistribution mechanism.

We are aware that many pharmaceutical manufacturers are in the process of developing their own "national" program for reimbursement to Medicaid agencies. Common to almost all of them is that for a Medicaid agency to be eligible for the proposed discount, they must agree to make available all of that company's drug products. California is opposed to that concept as it violates our strong belief in the appropriateness of a drug formulary. That is not to say we may not, in the negotiation process, agree to add all of a company's existing single source products, or to favorably or expeditiously review new FDA product approvals; just that as a manufacturer's condition of being eligible for a rebate, it is not an appropriate requirement for states with formularies. I would point out that our contracts *do not* adopt these policies.

Finally, I would like to address the issue of the appropriateness or need for Federal legislation. I believe that Federal legislation addressing the issue of Medicaid agencies achieving some level of discount from pharmaceutical manufacturers is appropriate, and probably even necessary. However, I believe that the following general guidelines may be sufficient, thereby allowing states the latitude to work out individual programs that best meet their needs:

1. All state Medicaid agencies should achieve some minimum aggregate level discounts from pharmaceutical manufacturers.
2. States should have the flexibility to have a formulary or not, so long as drugs not readily available remain obtainable through some type of exception (prior approval) process.
3. States with an existing mechanism for obtaining discounts from pharmaceutical manufacturers should be allowed to retain their program so long as they meet the conditions specified above.

I hope that this testimony is helpful. I am available to answer any questions you may have. Thank you.

Examples of Single Source Drugs - Price Paid Comparison

Drug Name	AWP or Direct Price	Medi-Cal Pays	General Services	LA County	Veterans Admin	Lowest	Percent Difference
Capoten 12.5mg Tablet	$32.50	$32.50		$32.50	$28.77	$28.77	13%
Capoten 25mg Tablet	$35.78	$35.78		$35.78	$30.27	$30.27	18%
Capoten 50mg Tablet	$59.65	$59.65		$59.65	$51.58	$51.58	16%
Carafate 1gm Tablet	$50.63	$48.10		$41.70	$28.51	$28.51	69%
Cardizem 30mg Tablet	$70.00	$66.50		$25.00	$17.72	$17.72	275%
Cardizem 60mg Tablet	$48.44	$46.02		$39.90	$28.95	$28.95	59%
Ceclor Pulvule 250mg	$149.08	$149.08		$116.10	$55.67	$55.67	168%
Clinoril 150mg Tablet	$65.61	$65.61	$60.53	$65.61	$58.77	$58.77	12%
Clinoril 200mg Tablet	$80.63	$80.63	$74.38	$80.63	$45.39	$45.39	78%
Compazine 25mg Supp	$22.50	$21.38		$15.04	$11.65	$11.65	83%
Dilantin Infatab 50mg	$9.48	$9.48	$6.93	$8.29		$6.93	37%
Feldene 20mg Capsule	$143.02	$143.02		$143.02	$85.69	$85.69	67%
Geocillin 382 Mg Tablet	$106.68	$106.68			$64.94	$64.94	64%
Glucotrol 10mg Tablet	$36.18	$36.18	$32.20	$33.81	$26.39	$26.39	37%
Glucotrol 5mg Tablet	$19.71	$19.71	$17.54	$18.42	$14.44	$14.44	36%
Halcion 0.25mg Tablet	$36.49	$36.49	$34.10	$35.76	$9.98	$9.98	266%
Haldol Decanoate 50mg/ml Ampule	$230.93	$219.38	$143.00	$151.58	$137.54	$137.54	60%
Imuran 50mg Tablet	$79.32	$75.35		$66.97	$58.96	$58.96	28%
Klonopin 1mg Tablet	$52.72	$50.08			$42.47	$42.47	18%
Lo/Ovral Tablets - 21's	$16.17	$16.17	$1.75			$1.75	824%
Lo/Ovral Tablets -28's	$16.37	$16.37	$1.75	$1.75		$1.75	835%
Lopressor 100mg Tablet	$59.61	$56.63	$39.03	$46.40	$21.49	$21.49	164%
Lopressor 50mg Tablet	$39.31	$37.34	$24.13	$30.32	$11.94	$11.94	213%
Methergine 0.2mg Tablet	$30.90	$29.36		$25.75		$25.75	14%
Naprosyn 250mg Tablet	$60.65	$57.62	$47.67	$49.10	$30.16	$30.16	91%
Naprosyn 375mg Tablet	$77.24	$73.38	$60.70	$62.53	$35.23	$35.23	108%
Naprosyn 500mg Tablet	$95.22	$90.46	$74.83	$77.08	$42.17	$42.17	115%
Ovral-21 Tablet	$21.53	$21.53	$1.75	$1.75		$1.75	1,130%
Parlodel 2.5mg Tablet	$100.98	$95.93	$76.67	$84.17	$60.43	$60.43	59%
Plaquenil 200mg Tablet	$75.73	$71.94		$59.60	$43.11	$43.11	67%
Premarin Vaginal Cream w/ Applicator	$17.29	$17.29	$6.70		$5.47	$5.47	216%
Procardia 10mg	$36.04	$36.04	$25.90	$32.14	$22.45	$22.45	61%
Procardia 20mg	$64.86	$64.86		$57.85	$37.16	$37.16	75%
Retrovir 100mg Capsule	$144.23	$137.02		$121.77	$120.19	$120.19	14%
Sinemet-25/100 Tablet	$38.08	$38.08			$34.84	$34.84	9%
Tagamet 300mg Tablet	$57.65	$54.77	$38.59	$38.59	$27.65	$27.65	98%
Tagamet 400mg Tablet	$58.45	$55.53	$44.20	$44.20	$29.87	$29.87	86%
Timoptic 0.5% Ocumeter 5ml	$10.78	$10.78	$10.17	$10.78	$9.48	$9.48	14%
Tolectin DS 400mg Capsule	$68.92	$65.47		$50.60	$18.54	$18.54	253%
Tri-Norinyl Tablet 28's	$16.30	$15.49		$0.01		$0.01	154,750%
Vasotec 10mg Tablet	$59.83	$59.83		$59.83	$56.68	$56.68	6%
Vasotec 5mg Tablet	$56.97	$56.97		$56.97	$54.03	$54.03	5%
Zovirax 200mg Capsules	$67.09	$63.74		$54.00	$60.45	$54.00	18%

OPEN DRUG FORMULARIES

MYTHS AND MISCONCEPTIONS

DEPARTMENT OF HEALTH SERVICES

I. Purpose of Formularies

A drug formulary is a list used to identify preferred drugs that are covered under a given health care program. For many years, hospitals, private health care programs, and governmental health agencies throughout the country have been using drug formulary systems in their administration of pharmaceutical service programs. The purpose of these formularies is to improve the quality and control the cost of drug therapy. Since the medical care of patients in any health care organization is often dependent upon the effective use of drugs, the evaluation and selection of specific drugs has become the standard process for providing appropriate and economical drug therapy. The formulary system within hospitals has become so important that such a system is now a requirement or recommendation of Title 22 of the California Code of Regulations, the Code of Federal Regulations, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

> Hospitals, private health care programs, and governmental health agencies throughout the country have been using drug formulary systems in their administration of pharmaceutical service programs for years.

II. California's Medi-Cal Drug Formulary

The Medi-Cal pharmaceutical program maintains the Medi-Cal Drug Formulary, which contains approximately 500 drugs of various types to be used in the treatment of outpatient Medi-Cal beneficiaries at a cost, for just the drugs, of over $500 million per year. The Formulary is semi-restrictive (semi-closed) in nature, like many public and private hospital outpatient programs, but not the completely restrictive (closed) formulary system used in some state Medicaid programs. This difference is significant because a semi-restrictive formulary provides coverage for drugs not listed, whereas a closed formulary does not. In this regard, nearly all commercially available drugs not listed on the Formulary are covered by the Medi-Cal Program, subject to prior authorization from a Medi-Cal consultant. This process insures the availability of medically necessary drugs not listed on the Formulary.

> The Medi-Cal Drug Program spends over $500 million annually. Nearly all commercially available drugs not on the Formulary are covered by the program, subject to prior authorization.

A few drugs listed on the Formulary are restricted to use for certain specified clinical conditions: other uses require prior authorization. Certain drugs on the Formulary that are typically prescribed for long-term use have minimum dispensing quantity requirements. This is to avoid excessive dispensing fees associated with inappropriately small prescription quantities. In order to control inappropriately large prescription quantities, all drugs covered by the program have a uniform maximum dispensing quantity limitation.

The Formulary is kept up to date by the ongoing addition of newer drug products and deletion of older, inferior drug products. These changes take place three times a year, subsequent to meetings of the Medical Therapeutics and Drug Advisory Committee. This Committee is an "outside" advisory group that makes recommendations to the Director of the Department of Health Services (DHS) on changes to the Formulary. The Committee is comprised of practicing physicians.

pharmacists and one pharmacologist. In addition to the Committee, professional staff of DHS make recommendations to the Director after first performing a thorough review of the drugs under consideration. This review includes a review of public hearing testimony, reference to current medical literature, and contacts with physician specialists within the medical schools and private practice settings. The criteria which DHS uses in considering a drug addition or deletion are the drug's relative safety, effectiveness, misuse potential, and cost compared to Formulary drugs, and its ability to fill an unmet need on the Formulary.

The criteria which DHS uses in considering a drug addition or deletion are the drug's relative safety, effectiveness, misuse potential, and cost compared to Formulary drugs, and its ability to fill an unmet need on the Formulary.

In regard to level of care provided by a formulary system, it is noteworthy that these five criteria provide a mechanism to screen drugs from the Formulary which do not have an overall advantage over existing Formulary drugs. For example, a drug that is equally safe and effective but more expensive than existing Formulary drugs may not be added to the Formulary because the cost disadvantage is predominant.

III. Unsuccessful Attempts to Discredit Restricted Formularies

The Pharmaceutical Manufacturers Association (PMA) has recently sponsored studies of various states' Medicaid programs that have attempted to show that unrestricted or "open" drug formularies are more cost-effective and provide higher quality of health care than restrictive drug formularies such as Medi-Cal. The motivation to do these studies, of course, is not to find ways to save the states' Medicaid programs money, but rather to increase the utilization of the drugs they market, and thereby expand their market share.

> The PMA motivation to do these studies is not to find ways to save the states' Medicaid programs money, but to increase utilization of the drugs they market and consequently, their profits.

One such study is reviewed here because it has been reported to be the strongest study to date of the effects of restrictive formularies on Medicaid expenditures. In order to understand why there still remains no proof to the authors' claims. one must examine closely the methodology and the associated assumptions made. as well as their analysis of the data, and then see how this relates to the Medi-Cal program.

The study to be reviewed here was authored by W. Moore and R. Newman of the Department of Economics. Louisiana State University. It is titled. *An Economic Analysis of State Medicaid Formularies: Implications for the Recent Changes in the Louisiana Formulary.* This study purposes to examine the economic effects of restrictive drug formularies in 47 state Medicaid programs, with implications on the restrictive formulary adopted by the State of Louisiana in 1988.

This study is based on a statistical analysis of total Medicaid vendor payments for eleven types of services (Inpatient Hospital. General and Mental: Skilled Nursing Facilities; Intermediate Care. Mentally Retarded and "All Other"; Physician Services; Other Practitioner; Outpatient Hospital: Clinic Services; and Prescribed Drugs). Their analysis is based on a multivariate regression model that considers the simultaneous influence of many program characteristics on Medicaid costs. In essence, this analysis attempts to isolate the effect of a particular variable such as formulary status (i.e. restricted or unrestricted) on a variable such as vendor payments for prescribed drugs or inpatient hospitalization, while keeping other variables constant, such as total resident population, *per capita* income, unemployment rate, and number of persons in each state over the age of 65.

States with high Medicaid expenditures are more likely to adopt restricted formularies. The study, however, incorrectly assumes that the reverse is true: restricted formularies result in high expenditures.

"Service Substitution Hypothesis"

Three variations of their basic model are presented that provide estimates of total Medicaid expenditures in a state whose formulary is restrictive in nature. These estimates show that Medicaid expenditures in states with restrictive formularies will be anywhere from 4.1 to 30.5 percent higher than they would if their formulary was open. The reason why this might occur, they hypothesize, is due to a "service substitution" effect. This service substitution hypothesis is based on a theoretical discussion in which the elimination of certain types of treatment (in this case the removal or restriction of certain drugs from a formulary) may cause physicians and patients to substitute other forms of therapy. Since if the initial therapy requested (e.g. the drug of choice) is not available, *any* substitute will therefore be of lesser quality and can result in higher Medicaid expenditures (e.g. higher doses for longer treatment periods of the substitute drug may be required).

The estimate of a 4.1 to 30.5 percent increase is questionable. Moore-Newman themselves state that the largest impact of 30.5 percent may be biased and misleading. Therefore, they believe an increase between 4.1 to 15.5 percent to be more realistic. These figures are further questioned in another PMA-sponsored study done at Vanderbilt University in Tennessee by F. Sloan. The purpose of the Tennessee study was to determine the fiscal impact of their restrictive Medicaid formulary on Medicaid expenditures based on Moore-Newman's methodology and findings. According to Sloan, only the model which predicts a 4.1 percent increase in Medicaid expenditures merits attention. However, Sloan acknowledges that this 4.1 percent increase failed to achieve a sufficiently high level of statistical significance. In other words, "the positive impact of a restrictive formulary estimated by the regression analysis could have occurred by chance". Even so, Sloan used Moore-Newman's flawed methodology and findings and, not surprisingly, came to the same conclusions as Moore-Newman.

> The study failed to establish a direct cause/effect relationship between restricted formularies and increased total Medicaid expenditures.

The Moore-Newman conclusions suggest that restricting the use of drugs will result in increased overall programs costs. However, the study failed to establish a direct cause/effect relationship between restricted formularies and increased total Medicaid expenditures. Furthermore, even if a cause/effect relationship were to be found in these restrictive-formulary states, these conclusions could not be extrapolated to the Medi-Cal pharmaceutical program because they assumed that all restrictive formularies eliminate entire coverage for certain drugs or drug-categories. in contrast to the Medi-Cal program's semi-restrictive nature (i.e. medically necessary drugs not on the Formulary are available via prior authorization).

Formulary Status: "Restricted vs. Unrestricted"

While the purpose of this study was to provide a method for isolating the effect of a particular independent variable (i.e. restrictive drug formularies) on various types of vendor payments, they have not adequately defined "restrictive drug formulary", thereby causing all subsequent data analysis and review to be biased and misleading.

To appreciate the seriousness of this error, one must closely examine the "formulary status" of the states included in the analysis. Of the 47 states included in this cross-sectional analysis, there are 21 states that claim to have a Medicaid drug formulary (19 with a restricted drug list and two which claim "no drug list, but certain categories are excluded from reimbursement"). The remaining 26 states claim to not have a drug formulary (only two states claim that "all legend drugs are reimbursed", the remaining 24 states have "no drug list, but certain categories are excluded from reimbursement).

The study fails to define "restricted" drug formulary, therefore, their analysis is questionable if not invalid.

The above description is included not to confuse the reader, but to show that "restricted formulary status" is not, according to the data, a simple yes/no condition as the authors define in their methodology where formulary status was defined as "restrictive" or "otherwise". Therefore, out of 47 states surveyed, only two can claim to have open or unrestrictive drug formularies. Since no raw data is presented in their paper, it is unclear which states or how many states they included in the "restricted" category. This is particularly confusing since one of the tables presented in the paper showed all the states were divided into the following three distinct categories: "Open Formulary", "Mild Restrictions" and "Restricted Formulary". One thing does become clear in this regard though, and that is each state has developed a unique Medicaid program within a broad framework of federal guidelines and that any gross comparisons between them specifically regarding formulary status are highly questionable.

State-specific Variations in Medicaid Programs

It is no surprise then that out of 50 states, there are in fact 51 (including the District of Columbia) different Medicaid programs providing a multitude of services for 51 diverse patient populations in 51 different economic markets.

There are even variations in Medicaid expenditures within states that make gross generalizations risky. For example, in San Francisco County, Medi-Cal pharmacy costs are 25 percent higher per recipient than Merced County. If we consider the differences between these two counties for Medi-Cal eligible patients, the figure is 52 percent higher for San Francisco County. This variation is seen in spite of the fact that eligibility criteria, benefit structure, reimbursement methodologies, etc., are the same in both counties. In this case, the major reason for the variations observed is due to differences in the patient population.

> There are variations in Medicaid expenditures that make gross generalizations risky. The Moore-Newman study fails to take these state-specific factors into consideration when performing the multivariate regression analysis.

The Moore-Newman study does not take any of these state-specific conditions into account. Even if they did, they could never control for all the possible variations that are in a constant state of change. It is not possible to ascertain the effect of restrictive drug formularies or total program expenditures by the methodology employed by Moore-Newman. Medicaid program characteristics vary so widely from state to state that virtually any multivariate regression analysis approach that does not take these state-specific factors into consideration must be considered flawed. Since we have no reliable way to make fair comparisons between state Medicaid programs using a multivariate regression methodology in regard to overall expenditures versus formulary status, we are left with making comparisons between states based on drug expenditures and total expenditures per Medicaid recipient. As seen in Table 1, California spends less per Medicaid recipient for drugs and spends less per recipient for over-all program expenditures than almost any other state.

As stated earlier, the Moore-Newman study results are based on a statistical analysis that uses the theoretical concept of health service substitution to explain their findings. In an attempt to add more support to this hypothesis, these authors further state that, "to the extent that new and higher quality drugs are excluded from a drug formulary, or at least delayed in entering the market under a restrictive formulary, the potential health care status of Medicaid patients will be diminished".

Through their marketing strategies, the pharmaceutical industry would like the public to believe that all new drugs equal improvements in health care.

Many proponents of unrestrictive or open drug formulary systems have also postulated that formulary restrictions are unnecessary because only the most safe and efficacious drugs are approved for marketing by the FDA and only the most superior drugs are prescribed by physicians. This misconception is a major force behind the marketing strategies of the pharmaceutical industry, which would like nothing better than for the public to believe that a greater number of new drugs available equates to better health care.

IV. New Drug Products vs. Older Medications

Currently, the FDA approves the addition of new drugs to the American market solely on the basis of safety and efficacy. This approval is not contingent upon comparing the new drug that is seeking FDA approval with other drugs of similar therapeutic value. This is why a formulary system is so valuable. The FDA *does* however, classify each new drug according to its chemical type and therapeutic potential. Of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, only 12, or 3 percent of the total were rated type "A", designating these as "Important therapeutic gains". Only 44, or 13 percent, were rated type "B" ("Modest therapeutic gains"). The remainder of these new drugs, 292 or 84 percent were rated Type "C" (providing "Little or no therapeutic gain"). Within the health care profession, drugs that provide little or no contribution to existing therapies are known as "me-too" drugs. As seen from the above example, the vast majority of new drugs coming to market in America fall into this "me-too" category. However, the prices established for these "me-too" products are anything but "little" or even "modest". It is well known, even in the public sector, that new drugs are priced higher and in most cases substantially higher than older medications.

Of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, the FDA rated only 3 percent as "Important therapeutic gain". Furthermore, 84 percent were rated as providing "Little or no therapeutic gain".

Unfortunately, few physicians have the opportunity to evaluate various drug products on a scientific or cost basis. The Medi-Cal formulary system provides an objective basis for prescribing decisions because DHS staff explore the scientific bases of competing claims and also consider drug alternatives that are not actively promoted but which represent good quality lower cost therapy. By screening out drugs of lesser quality, the Formulary serves as a useful guide to physicians for prescribing the most appropriate drug therapy.

New drug products have also been promoted to be safer alternatives than older medications. However, this increased safety has not always been realized in clinical practice. While the FDA approves drugs based in part on their safety profile, the data that is available to them for review does not always contain enough cumulative patient exposure time to pick up a relatively rare adverse reaction. It is not unusual for a new drug product to be removed from the American market a few months or years after its release due to an unusual but potentially lethal side effect. Examples of drugs that have met such a fate in the last few years are Selacryn, Zomax, Suprol, Oraflex, and Merital.

FDA approval is not contingent upon comparing new drugs to existing drugs with similar values. An approved new drug is not necessarily an improvement over existing drugs in terms of efficacy, safety, or cost.

In April 1989, the FDA announced that two drugs widely used to treat heartbeat irregularities (Tambocor and Enkaid) were linked to an abnormally high rate of death in a control group study. In the last few years, the antibiotic Moxam has seen a decrease in utilization which most probably is due to episodes of bleeding. The above mentioned heart medications and antibiotic have not been removed from the market (nor do we want to imply that they should be), but they serve as examples of drugs that were found to have unexpected risks associated with their use that were not fully appreciated until after the drug became widely prescribed. In fact, the complete adverse reaction profile of virtually all drugs is not fully appreciated until a drug has been on the market for a number of years. One should not imply from this that we believe that older drugs are inherently safer than newer drugs but the fact remains that the more a medication is used, the better we know its adverse reaction profile. To reiterate, just because a new drug is available does not necessarily mean it will be an improvement over existing drugs in terms of efficacy or safety. This is contrary to what drug manufacturers are saying about their products, particularly when they are lobbying for an open drug formulary.

V. Consequences of an "Open" Medi-Cal Drug Formulary

As stated earlier, the purpose of a drug formulary is two-fold: to promote the appropriate use of drugs and to control the cost of drug therapy. Some of the consequences of an "open" Medi-Cal drug formulary become quite apparent when one reviews some specific cases of documented drug overutilization within the Medi-Cal Drug Program. Examples of such circumstances involves the overutilization of codeine products, the antianxiety drug Valium, and drugs used in the treatment of peptic ulcer disease. The overuse of these medicines is not just a local problem, but has been well established in the world-wide medical literature.

> The purpose of the Medi-Cal Formulary is to promote the appropriate use of drugs and control costs. Documented cases of drug overutilization plague open formularies.

Overutilization

In September 1973, the Department entered into a pilot project contract with the manufacturer of Valium. Under the terms of the project, the manufacturer guaranteed that the State's expenditures for psychotherapeutic drugs (major tranquilizers, antidepressants, combinations thereof, and certain barbiturates) would be lessened if the restrictions on the use of Valium were removed. This however, was never realized. Due to dramatic increases (on the order of $3.5 million during the first year) in program costs, these restrictions had to be reinstituted.

In 1987, in an effort to decrease the overutilization of codeine products, the Department placed restrictions on their use. Since that time, the Department has realized very significant cost savings (currently between four and five million dollars per year) due to a decrease in the number of prescriptions for codeine-containing products. If the Department had been wrong in its assumption that such products were being prescribed beyond medical necessity, the utilization of the prior authorization system would have increased proportionately. This increase however, has not occurred.

Inappropriate Utilization

The medical literature has, for a number of years, provided many examples of the inappropriate use of antiulcer drugs. Commonly identified problems and associated factors include: use for unacceptable indications; long term use without diagnostic procedures being performed; incorrect dosage regimens, and most frequently, acute dosage levels prescribed for extended periods of time. The indiscriminate use and overutilization of these drugs is a problem experienced by health care administrators throughout the country in both inpatient and outpatient settings, and has been identified as a very significant problem occurring within the Medi-Cal population as well. Other state Medicaid programs have already instituted limitations on the use of antiulcer medications to control expenses and promote rational drug therapy.

In an effort to achieve more appropriate drug utilization and reduce the cost of treating peptic ulcer disease, the Department is currently proposing limitations on the use of the drugs that are commonly overprescribed in this area. Recently, the Medical Therapeutics and Drug Advisory Committee agreed with the Department's proposals and voted unanimously to recommend to the Director of Health Services to adopt such limitations.

Fiscal Implications

Removing all restrictions on drug usage by changing from a semi-restrictive formulary to an "open" formulary would result in dramatic increases in utilization of these and other drug products.

An open Medi-Cal Formulary would cost the California tax payer at least an additional $413 million.

Recently, DHS undertook the task of assigning a dollar value to the use of the Formulary in an unrestricted condition (Attachment 1). Specifically, a fiscal estimate was developed for the hypothetical change from a semi-restrictive Formulary to an unrestricted or open Formulary. The greatest impact will be on Medi-Cal expenditures for the ingredient cost of non-formulary drugs. The vast majority of these drugs fall into the "me-too" category that actually add little or no therapeutic advantage over existing drugs on the Formulary. The fiscal impact of such a change would increase annual program expenditures amounting to at least $413,953,000. This amount, however, does not take into account the increase in drug costs that would come from removing the restrictions on antianxiety drugs such as Valium, codeine products, and other drugs that have a high potential for abuse.

VI. CONCLUSION

The Medi-Cal Drug Formulary serves as a guide to physicians on appropriate drug therapy at a reasonable price. The Formulary is an effective means of minimizing payment for therapeutically disadvantageous and/or overpriced drugs while reducing the potential for overutilization of drugs. Its semi-restrictive nature provides the flexibility for coverage of unlisted drugs in medically necessary circumstances. Although the adequacy of the Formulary in meeting its objective has been questioned, such challenges are without merit. Therefore, the Formulary remains as an effective tool for controlling drug program expenditures without sacrificing quality of care and should remain in place.

> The Medi-Cal Drug Formulary is an effective means of minimizing payment for therapeutically disadvantageous and/or overpriced drugs while reducing the potential for overutilization of drugs.

Table I
Relationship Between Total Health Care Costs Per Person and Drug Expenditures Per Person
A Comparison of State Medicaid Programs

	Total Cost Per Recipient	Drug Cost Per Recipient	Ranking: Total Cost Per Recipient	Ranking: Drug Cost Per Recipient
Mississippi	$1,133.00	$166.00	1	4
West Virginia	1,282.00	143.00	2	1
California	1,422.00	163.00	3	3
Alabama	1,454.00	213.00	4	20
Michigan	1,635.00	191.00	5	13
Kentucky	1,670.00	146.00	6	2
Montana	1,681.00	168.00	7	5
Hawaii	1,710.00	171.00	8	7
South Carolina	1,730.00	180.00	9	10
Oregon	1,755.00	233.00	10	28
Group Average	$1,547.20	$177.40		
Illinois	1,780.00	179.00	11	9
Louisiana	1,790.00	265.00	12	42
Missouri	1,810.00	194.00	13	14
Texas	1,832.00	168.00	14	6
Tennessee	1,855.00	260.00	15	40
Arkansas	1,904.00	206.00	16	18
Florida	1,944.00	261.00	17	41
Kansas	1,984.00	204.00	18	16
Georgia	2,058.00	291.00	19	47
New York	2,066.00	258.00	20	38
Group Average	$1,902.30	$228.60		
Pennsylvania	2,071.00	231.00	21	26
Iowa	2,073.00	223.00	22	25
Ohio	2,111.00	201.00	23	15
Washington	2,113.00	180.00	24	11
Utah	2,153.00	185.00	25	12
Nebraska	2,160.00	253.00	26	37
Vermont	2,209.00	242.00	27	32
Virginia	2,318.00	267.00	28	45
North Dakota	2,331.00	266.00	29	43
Oklahoma	2,377.00	215.00	30	22
Group Average	$2,191.60	$226.30		

	Total Cost Per Recipient	Drug Cost Per Recipient	Ranking: Total Cost Per Recipient	Ranking: Drug Cost Per Recipient
Wisconsin	2,442.00	279.00	31	46
Colorado	2,585.00	241.00	32	30
Nevada	2,595.00	217.00	33	23
Maryland	2,634.00	212.00	34	19
Idaho	2,656.00	243.00	35	33
Delaware	2,711.00	178.00	36	8
Maine	2,715.00	252.00	37	36
Alaska	2,884.00	213.00	38	21
South Dakota	3,000.00	249.00	39	34
New Mexico	3,223.00	233.00	40	27
Group Average	$2,744.50	$231.70		
Minnesota	3,296.00	236.00	41	29
Rhode Island	3,382.00	219.00	42	24
Indiana	3,445.00	363.00	43	49
North Carolina	3,625.00	250.00	44	35
Massachusetts	3,682.00	260.00	45	39
Dist. of Columbia	3,727.00	206.00	46	17
Connecticut	3,930.00	267.00	47	44
New Jersey	4,163.00	241.00	48	31
New Hampshire	5,004.00	324.00	49	48
Group Average	$3,806.00	$262.89		

ATTACHMENT 1

FISCAL ANALYSIS OF PROPOSED LEGISLATION FOR AN OPEN MEDI-CAL DRUG FORMULARY AND EXPANDED VITAMIN COVERAGE

Proposed legislation would extend Formulary coverage to all drugs approved by the Food Drug Administration (FDA), expand coverage for multi-vitamins, and initiate a $1 co-payment for all drug prescriptions (except for recipients under 21 years of age, long term care patients and for family planning prescriptions).

I. OPEN MEDI-CAL DRUG FORMULARY

Proposed legislation would eliminate the current Medi-Cal Drug Formulary process, and would allow for any drug approved by the FDA to be covered by Medi-Cal. The Medi-Cal Drug Formulary is a listing of drugs that are, with some exceptions, covered by the Medi-Cal program without prior authorization. Drugs are periodically added to or deleted from the Medi-Cal Drug Formulary based on petitions filed by drug manufacturers. The petitions are separately reviewed by Department staff and by the Medical Therapeutics and Drug Advisory Committee which recommend to the Director of Health Services as to which formulary changes should be approved. The Director makes the final decision after a public hearing has been held on each recommended petition. Drugs not on the Formulary are covered if treatment authorization requests (TARS) are approved.

The greatest impact will be on Medi-Cal expenditures for the ingredient cost of non-formulary drugs. This analysis projects a conservative impact because it assumes no increase in total Medi-Cal prescriptions, but rather a substitution in the usage of formulary-listed drugs by non-formulary drugs. Although the analysis assumes no increase in prescriptions, there are drug categories currently not available on the Formulary, or whose availability is very restricted : e.g., laxatives, anti-anxiety and anti-cholesterol drugs. These drugs would become readily available through an open formulary which would greatly increase costs by several millions of dollars. Another concern not addressed in this analysis is that quantity restrictions would be removed which could result in costly abuse of certain drugs; e.g., codeine and anti-anxiety drugs. Although these costs are impossible to quantify at this time, they would have a significant cost impact. There would also be some administrative savings in that pharmaceutical consultants now reviewing TARS and updating the Formulary would not be required.

Assumptions:

1. The top 200 drugs most often prescribed in the United States account for 52.1% of all drug prescriptions (Source: Pharmacy Times, April, 1989). Based on the utilization data presented in the article, non-formulary drugs were estimated to account for 40.0% of all drug prescriptions.

2. Assume that the nationwide utilization rate of 40.0% for non-formulary drugs would also be the substitution rate for these drugs in the Medi-Cal program given an open Formulary.

3. Total Medi-Cal drug prescriptions in FY 1988-89 were 29,317,000.

4. Non-Formulary Medi-Cal drug prescriptions approved through prior authorization were 297,308 in FY 1988-89.

5. The number of Formulary drug prescriptions to be substituted by Non-Formulary drugs as a result of an open formulary is computed as follows:

29,317,000	Total Medi-Cal Prescriptions
x .40	Non-Formulary Substitution Factor
11,726,800	Total Non-Formulary Prescriptions
- 297,300	Less Current Non-Formulary Approvals
11,429,500	Net Prescriptions being Substituted

6. Recent reports (July through Sept. 1989) on cost per prescription show an average prescription cost of $15.47 for Formulary drugs and $65.71 for Non-Formulary drugs.

7. The professional fee component per prescription is $4.05. The difference between the professional fee component and the cost per prescription is the drug ingredient cost. The higher ingredient cost of non-Formulary drugs is the component which will result in additional Medi-Cal costs as a result of implementing an open Formulary. The ingredient cost is calculated as follows:

	Formulary	Non-Formulary
Total	$15.47	$65.71
Professional Fee	- 4.05	- 4.05
Ingredient Cost	$11.42	$61.66

8. Part of the cost difference between Formulary and non-Formulary drugs is due to the fact that the quantity of drugs dispensed per prescription decreases when a drug is added to the Formulary. Based on data obtained for drugs before and after their addition to the formulary, the quantity of drugs dispensed is 31% higher before a drug is listed on the Formulary. This computes to a decrease of 24% in quantity prescribed when a drug is added to the Formulary.

$61.66	Cost per Non-Formulary Prescription
x (1-.24)	Quantity per Prescription Factor
$46.86	Adjusted Cost per Non-Formulary Prescription

9. The net cost per prescription to substitute a Formulary-listed drug with a non-Formulary drug is computed as follows:

$46.86	Cost per Non-Formulary Prescription
-11.42	Cost per Formulary Prescription
$35.44	Net Additional Cost per Prescription

10. Total cost to the Medi-Cal program of an open drug Formulary is:

11,429,500	Total Prescriptions being Substituted
x $35.44	Net Cost per Substituted Prescription
$405,061,500	Additional Medi-Cal Cost
$202,530.750	General Funds

11. The County Services Medical Program (CMSP), which covers county medically indigent adults and for whom the State reimburses at cost for, provides the same drug coverage as does the Medi-Cal program. Drug expenditures under this program is equivalent to .563% of Medi-Cal expenditures. Thus, the CMSP cost of an open Formulary is:

$405,061,500	Additional Medi-Cal Cost
x .00563	CMSP Factor
$ 2,280,500	Additional CMSP Cost
$ 2,280,500	General Fund Cost

II. EXPANSION OF VITAMIN COVERAGE

Proposed legislation would extend formulary coverage of multi-vitamins for children up to and including seven years of age, and geriatric vitamins for recipients sixty-five years of age and older.

Assumptions:

1. Currently, age group 0-5 years totals 558,324 in eligibles, and costs $2,691,000 annually for multi-vitamin therapy.

2. Adding coverage to age group 6-7, which total 183,396 in eligibles, would increase the pediatric population for multi-vitamins and costs by 33%.

$2,691,000	Current Multi-vitamin Cost for Ages 0-5
x .33	Factor for Addition of Ages 6-7
$ 888,000	Total Cost for Adding Coverage to Ages 6-7

3. Current eligible counts of age group 65 and over total 502,039.

4. Assume a $9.50 cost per prescription for 100 vitamins (a three month supply).

5. Assume 30% of the 65 and over age group will receive vitamin therapy.

502,039	Total Eligibles for Ages 65 and Over
x .30	% of Eligibles that will Receive Vitamins
x $ 9.50	Cost per Prescription
x 4	Number of Prescriptions per Year
$5,723,000	Total Cost for Adding Coverage to Ages 65+

$ 888,000	Total Cost for Adding Coverage to Ages 6-7
$5,723,000	Total Cost for Adding Coverage for Ages 65+
$6,611,000	Total Cost for Expanded Vitamin Coverage

III. COPAYMENT

Proposed legislation would require recipients to pay a $1 copayment for drug prescriptions, except for recipients under 21 years of age, long term care patients, or family planning or pregnancy related prescriptions. This copayment provision is marginally out of compliance with federal regulations which could jeopardize federal financial participation (FFP) for all drug expenditures. Current federal fund costs for drugs in jeopardy total $302,234,000. An open drug formulary would jeopardize an additional $205,836,250 in FFP for a total additional General Fund cost of $508,070,250.

SUMMARY OF FISCAL IMPACT:

	Total Funds	General Funds
Open Medi-Cal Formulary Costs	$405,061,500	$202,530,750
CMSP Costs	$ 2,280,500	$ 2,280,500
Expanded Vitamin Coverage	$ 6,611,000	$ 3,305,500
Total Additional Costs	$413,953,000	$208,116,750

Additional General Fund costs of $508,070,250 could occur annually if federal financial participation were to be lost for all Medi-Cal drug expenditures because the copayment provisions are not fully in compliance with federal Medicaid provisions. There are also significant but indeterminate costs which would occur through increased utilization of laxatives, anti-anxiety, and cholesterol-lowering drugs, and through loss of quantity restrictions for abusable drugs such as anti-anxiety drugs and codeine. In addition to these indeterminate costs, there are some administrative savings associated with the elimination of pharmaceutical consultants now reviewing TARS.

MEDI-CAL DRUG DISCOUNT PROGRAM

The Legislature finds and declares as follows:

(a) It is the intent of the Legislature to improve the health status of Medi-Cal beneficiaries at the least possible cost to the state.

(b) The Medi-Cal program is a large purchaser of drugs and should be entitled to employ usual business practices in securing drugs at discount prices.

(c) A customary business practice for drug manufacturers and distributors is to offer discount prices and rebates on drugs to their large volume purchasers, including other governmental agencies.

(d) In order to enable Medi-Cal to purchase drugs in the most cost-competitive manner and employ customary business practices, it is necessary to allow the State Department of Health Services to replace the Medi-Cal drug formulary with a list of contract drugs.

(e) It is the intent of the Legislature that the list of contract drugs contain a comprehensive mix of single-source and multiple-source drugs, sufficient to ensure beneficiary access to appropriate drug therapies. In addition, for persons with certain medical conditions, therapeutic equivalents are not interchangeable. Therefore, it is also the intent of the Legislature to ensure that within a therapeutic category, sufficient variety is available to accommodate medically necessary alternatives.

(f) The Legislature intends that Medi-Cal beneficiaries have available a comprehensive range of drug products and hereby directs the department to favorably review manufacturers' requests for drug product addition when those requests are accompanied with an acceptable best price contract offer, and the drug product otherwise meets the five criteria enumerated in subdivision (d) of Section 14105.39 of the Welfare and Institutions Code.

(g) It is the intent of the Legislature that the department improve the telephone access of providers to the current drug treatment authorization process. The department intends to meet this objective by expanding the resources available to the field offices, consistent with proposals included in the Budget Act of 1990. These additional resources are intended to increase availability of field office staff to providers. The Legislature further intends that the department respond to provider requests within 10 rings, or provide a secondary answering system to record provider calls. It is also intended that the department develop performance standards for responding to provider calls, consistent with the advances in technology the department is currently pursuing. In no event should these performance standards exceed eight working hours.

Section 14053.5 of the Welfare and Institutions Code is amended to read:
14053.5 For the purposes of the Medi-Cal Act, the terms "prescribed drug" and "prescription drug" shall not include any drug which, because of differing prices charged by the manufacturer on a discriminatory basis or discriminatory refusal to sell by the manufacturer, or both, is not available on the same terms and conditions to all providers of prescription services, or any drug which is found to be overpriced in comparison to another drug which has an equivalent therapeutic effect, unless the director determines that the drug is vital to the program and no acceptable substitute is available.

Before the director determines that any drug has an equivalent therapeutic effect in comparison to another drug, or is vital to the program and no acceptable substitute is available, he must have received a report to that effect from the Medi-Cal Contract Drug Advisory Committee.

Nothing is this section shall be construed to apply to quantity or other nondiscriminatory discounts available on the same terms and conditions to all providers of prescription services, to sales by competitive bidding to federal, state or local governmental agencies, or to sales to wholesalers so long as the manufacturer does not require or induce the wholesalers to make the drug available other than on the same terms and conditions to all providers of prescription services.

This section shall not be construed to deny reimbursement to hospitals for prescribed drugs furnished to inpatients or, unless the regulations provide to the contrary, to registered outpatients.

Section 14105.31 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.31. For purposes of the Medi-Cal contract drug list, the following definitions shall apply:

(a) "Single-source drug" means a drug which is produced and distributed under an original New Drug Application approved by the federal Food and Drug Administration. This shall include a drug marketed by the innovator manufacturer and any cross-licensed producers or distributors operating under the New Drug Application. A drug ceases to be a single-source drug when the same drug in the same dosage form and strength manufactured by another manufacturer is approved by the federal Food and Drug Administration under the provisions for an Abbreviated New Drug Application.

(b) "Best price" means the negotiated price, or the manufacturer's lowest price available to any class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, which contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits, based upon the manufacturer's commonly used package sizes for the drug.

(c) "Equalization payment amount" means the amount negotiated between the manufacturer and the department for reimbursement by the manufacturer, as specified in the contract.

(d) "Manufacturer" means any person, partnership, corporation, or other institution or entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of drugs, either directly or indirectly by extraction from substsnces of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, lsbeling, relabeling, and distribution of drugs.

(e) "Price escalator" means a mutuslly agreed upon price specified in the contract, to cover anticipated cost increases over the life of the contract.

(f) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that dste.

Section 14105.33 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.33. (a) The department may enter into contracts with manufacturers of single-source and multiple-source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and shall maintain a list of those drugs for which contracts have been executed.

(b) Contracts executed pursuant to this section shall be for the manufacturer's best price, as defined in Section 14105.31, which shall be specified in the contract, and subject to agreed upon price escalators, as defined in that section. In no event shall the department require a manufacturer to provide a price lower than its lowest price to any class of trade, organization, or entity. The contracts shall provide for an equalization payment amount, as defined in Section 14105.31, to be remitted to the department quarterly. The department shall submit an invoice to each manufacturer for the equalization payment amount, based on utilization data from the department's prescription drug paid claims tapes.

(c) In order that Medi-Cal beneficiaries may have access to a comprehensive range of therapeutic agents, the department shall ensure that there is representation on the list of contract drugs in all major therapeutic categories. Except as provided in subdivision (a) of Section 14105.35, the department shall not be required to contract with all manufacturers who negotiate for a contract in a particular category. The department shall ensure that there is sufficient representation of single-source and multiple-source drugs, as appropriate, in each major therapeutic category.

(d) (1) The department shall select the therapeutic categories to be included on the list of contract drugs, and the order in which it seeks contracts for those categories. The department may establish different contracting schedules for single-source and multiple-source drugs within a given therapeutic category.

(2) The department shall make every attempt to complete the initial contracting process for each major therapeutic category by January 1, 1993.

(e) In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(f) Contracts executed pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(g) The department shall provide individual notice to Medi-Cal beneficiaries at least 60 calendar days prior to the effective date of the deletion or suspension of any drug from the list of contract drugs. The notice shall include a description of the beneficiary's right to a fair hearing and shall encourage the beneficiary to consult a physician to determine if an appropriate substitute medication is available from Medi-Cal.

(h) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.35 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.35. (a) (1) On and after July 1, 1990, drugs included on the Medi-Cal drug formulary shall be included on the list of contract drugs until the department and the manufacturer have concluded contract negotiations or the department suspends the drug from the list of contract drugs pursuant to the provisions of this subdivision.

The department shall, in writing, invite any manufacturer with single-source drug products on the formulary as of July 1, 1990, to enter into negotiations relative to the retention of its drug or drugs. As to the issue of cost, the department shall accept the manufacturer's best price as sufficient for purposes of entering into a contract to retain the drug or drugs on the list of contract drugs.

If the department and a manufacturer enter into a contract for retention of a drug or drugs on the list of contract drugs, the drug or drugs shall be retained on the list of contract drugs for the effective term of the contract.

If a manufacturer refuses to enter into negotiations with the department pursuant to this subdivision, or if after 30 days of negotiation, the manufacturer has not agreed to execute a contract for a drug st the manufacturer's best price, the department may suspend from the list of contract drugs the manufacturer's single-source drug in question for a period of at least 180 days. The department shall lift the suspension upon execution of a contract for that drug. Consistent with the provisions of this section, the department shall delete the Medi-Cal drug formulary specified in paragraphs (b), (c), (d), and (e) of Section 59999 of Title 22 of the California Code of Regulations.

(2) On and after July 1, 1990, the director may retain a drug on the Medi-Cal list of contract drugs even if no contract is executed with a manufacturer, if the director determines that an essential need exists for that drug, and there are no other drugs currently on the formulary that meet that need.

(3) The director may delete a drug from the list of contract drugs if the director determines that the drug presents problems of safety or misuse. The director's decision as to safety shall be based upon published medical literature, and the director's decision as to misuse shall be based on published medical literature and the director's decision claims data supplied by the fiscal intermediary.

(b) Any reference to the Medi-Cal drug formulary by statute or regulation shall be construed as referring to the list of contract drugs.

(c) (1) Any drug in the process of being added to the formulary by contract agreement pursuant to Section 14105.3, executed prior to the effective date of this section, shall be added to the list of contract drugs.

(2) Contracts pursuant to Section 14105.3 executed prior to January 1, 1991, shall be considered to be contracts executed pursuant to Section 14105.33, and the department shall exempt the drugs included in these contracts from the initial therapeutic category review in which they would normally be considered.

(3) Nothing in this section shall be construed to require the department to discontinue negotiations into which it has entered with any manufacturer as of the effective date of this section. Contracts entered into as a result of these negotiations shall be exempt from the initial therapeutic category review in which they would normally be considered.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.37 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.37. (a) The department shall notify each manufacturer of drugs in therapeutic categories selected pursuant to Section 14105.33 of the provisions of Sections 14105.31 to 14105.42, inclusive.

(b) If, within 30 days of notification, a manufacturer does not enter into negotiations for a contract pursuant to those sections, the department may suspend or delete from the list of contract drugs, or refuse to consider for addition, drugs of that manufacturer in the selected therapeutic categories.

(c) If, after 120 days from the initial notification, a contract is not executed for a drug currently on the list of contract drugs, the department may suspend or delete the drug from the list of contract drugs.

(d) If, within 120 days from the initial notification, a contract is executed for a drug currently on the list of contract drugs, the department shall retain the drug on the list of contract drugs.

(e) If, within 120 days from the date of the initial notification, a contract is executed for a drug not currently on the list of contract drugs, the department shall add the drug to the list of contract drugs.

(f) The department shall terminate all negotiations 120 days after the initial notification.

(g) The department may suspend or delete any drug from the list of contract drugs at the expiration of the contract term or when the contract between the department and the manufacturer of that drug is terminated.

(h) Any drug suspended from the list of contract drugs pursuant to this section shall be subject to prior authorization, as if that drug were not on the list of contract drugs.

(i) Any drug suspended from the list of contract drugs pursuant to this section or Section 14105.35 for at least 12 months may be deleted from the list of contract drugs in accordance with the provisions of Section 14105.38.

(j) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.38 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.38. (a) (1) In the event the department determines a drug should be deleted from the list of contract drugs, the department shall conduct a public hearing, as provided in this section, to receive comment on the impact of removing the drug.

(2) (A) The department shall provide written notice 30 days prior to the hearing.

(B) The department shall send the notice required by this subdivision to the manufacturer of the drug proposed to be deleted and to organizations representing Medi-Cal beneficiaries.

(b) (1) The hearing panel shall consist of the Chief, Medi-Cal Drug Discount Program, who shall serve as chair, and the Medi-Cal Contract Drug Advisory Committee.

(2) The hearing shall be recorded and transcribed, and the transcript available for public review.

(3) Subsequent to hearing all public comment, and within 30 days of the hearing, each panel member shall submit a recommendation regarding deletion of the drug and the reason for the recommendation to the director.

(c) The director shall consider public comments provided at the hearing and the recommendations of each panel member in determining whether to delete the drug.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.39 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.39. (a) (1) A manufacturer of a new single-source drug may request inclusion of its drug on the list of contract drugs pursuant to Section 14105.33 provided all of the following conditions are met:

(A) The request is made within 12 months of approval for marketing by the federal Food and Drug Administration.

(B) The manufacturer agrees to negotiate a contract with the department to provide the drug at the manufacturer's best price.

(C) The manufacturer provides the department with necessary information, as specified by the department, in the request.

(D) The department had concluded contracting for the therapeutic category in which the drug is included prior to approval of the drug by the federal Food and Drug Administration.

(2) Within 90 days from receipt of the request, the department shall evaluate the request using the criteria identified in subdivision (d).

(b) Any petition for the addition to or deletion of a drug to the Medi-Cal drug formulary submitted prior to the effective date of this section, shall be deemed to be denied. A manufacturer who has submitted a petition deemed denied may request inclusion of that drug on the list of contract drugs provided all of the following conditions are met:

(1) The manufacturer agrees to negotiate for a contract with the department to provide the drug at the manufacturer's best price.

(2) The manufacturer provides the department with necessary information, as specified by the department, in the request.

(3) The manufacturer submits the request to the department prior to October 1, 1990.

(c) Any new drug designated as having an important therapeutic gain and approved for marketing by the federal Food and Drug Administration on or after the effective date of this section, shall immediately be included on the list of contract drugs for a period of three years provided that all of the following conditions are met:

(1) The manufacturer offers the department its best price.

(2) The drug is typically administered in an outpatient setting.

(3) The drug is prescribed only for the indications and usage specified in the federal Food and Drug Administration approved labeling.

(4) The drug is determined by the director to be safe, relative to other drugs in the same therapeutic category on the list of contract drugs.

(d) (1) To ensure that the health needs of Medi-Cal beneficiaries are met consistent with the intent of this chapter, the department shall, when evaluating a decision to execute a contract, and when evaluating drugs for retention on, addition to, or deletion from, the list of contract drugs, use all of the following criteria:

(A) The safety of the drug.

(B) The effectiveness of the drug.

(C) The essential need for the drug.

(D) The potential for misuse of the drug.

(E) The cost of the drug.

(2) The deficiency of a drug when measured by one of these criteria may be sufficient to support a decision that the drug should not be added or retained, or should be deleted from the list. However, the superiority of a drug under one criterion may be sufficient to warrant the addition or retention of the drug, notwithstanding a deficiency in another criterion.

(3) Notwithstanding paragraph (2) of this subdivision, when a manufacturer requests inclusion of a drug on the list of contract drugs pursuant to subdivision (a) or (b) of this section, as to the issue of cost, the department shall accept the manufacturer's best price as

sufficient for purposes of entering into negotiations for a contract to place the drug on the list of contract drugs if the following condition is met:

The course of therapy cost of the drug, as compared to the course of therapy cost of drugs within the same category currently on the list of contract drugs, would result in a savings to the drug portion of the Medi-Cal program if the drug were added to the list of contract drugs.

Nothing shall preclude the department from adding drugs to the list of contract drugs that do not meet the above-referenced condition.

(e) (1) A manufacturer of single-source drugs denied a contract pursuant to this section or Section 14105.33 or 14105.37, may file an appeal of that decision with the director within 30 calendar days of the department's written decision.

(2) Within 30 calendar days of the manufacturer's appeal, the director shall request a recommendation regarding the appeal from the Medi-Cal Contract Drug Advisory Committee. The committee shall provide its recommendation in writing, within 30 calendar days of the director's request.

(3) The director shall issue a final decision on the appeal within 30 calendar days of the recommendation.

(f) Changes made to the list of contract drugs, including those made pursuant to Section 14105.37, shall become effective no sooner than 30 days after publication of the changes in provider bulletins.

(g) Changes made to the list of contract drugs under this or any other section are exempt from the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), and shall not be subject to the review and approval of the Office of Administrative Law.

(h) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.4 of the Welfare and Institutions Code is repealed.

Section 14105.4 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.4. (a) The director shall appoint a Medi-Cal Contract Drug Advisory Committee for the purpose of providing scientific and medical analysis on drugs contained on the list of contract drugs. The duties of the committee shall be as follows:

(1) To review drugs in the Medi-Cal list of contract drugs and make written recommendations to the director as to the addition of any drug or the deletion of any drug from the list. These recommendations shall be in accordance with subdivision (d) of Section 14105.39.

(2) To review and report in writing to the director as to the comparative therapeutic effect of drugs in accordance with Section 14053.5.

(3) To prepare a fair, impartial, and independent recommendation in writing, regarding appeals from manufacturers made pursuant to subdivision (a) of Section 14105.39.

(b) The committee shall consist of at least one representative from each of the following groups:

(1) Physicians.

(2) Pharmacists.

(3) Schools of pharmacy or pharmacologists.

(4) Medi-Cal beneficiaries.

(c) Members of the committee shall be reimbursed for necessary travel and other expenses incurred in the performance of official committee duties.

(d) In order to provide sufficient scientific information and analysis in the therapeutic categories under review, the director may replace a representative if required for specific expertise.

(e) The director shall notify the committee of the decisions made on the recommendations.

(f) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.4 is added to the Welfare and Institutions Code, to read:

14105.4. (a) The department shall schedule and conduct a public regulatory hearing to consider the addition of a drug to, or the deletion of a drug from, the Medi-Cal drug formulary five working days subsequent to the Medical Therapeutic and Drug Advisory Committee meeting which shall meet at least every four months. The public hearing may consist of written testimony only, and the hearing record shall be closed at the end of the public hearing.

(b) The department shall make available 45 days prior to the public hearing the department's estimate of any anticipated costs or savings to the state from adding a drug product to, or deleting a drug product from, the Medi-Cal drug formulary.

(c) Whenever the department accepts a completed petition to add a drug product to the Medi-Cal drug formulary and it is not processed pursuant to Section 14105.9, it shall be scheduled for review at the next regularly scheduled Medical Therapeutic and Drug Advisory Committee meeting and public regulatory hearing, unless the meeting and hearing are scheduled to occur within 120 days, in which case the drug product may be scheduled for the following hearing.

(d) The director shall issue a final decision regarding the drug product and shall submit any regulation adding a drug product to, or deleting a drug product from, the Medi-Cal drug formulary to the Office of Administrative Law, along with the completed rulemaking record, within seven months after the hearing prescribed in subdivision (a). This section shall not, however, be construed in a manner which results in the disapproval or invalidation of a regulation for failure to comply with the time frames prescribed in this subdivision and subdivisions (a) and (c).

(e) (1) Except as provided in paragraph (2), the criteria used by the department in deciding whether a drug product shall be added to or deleted from the formulary shall be limited to the criteria adopted as department regulations. The criteria shall be specific and unambiguous.

(2) Notwithstanding paragraph (1), either of the following may be submitted by the manufacturer in lieu of the Summary Basis of Approval prepared by the federal Food and Drug Administration for that drug:

(A) The federal Food and Drug Administration's approval or approvable letter for the drug and federal Food and Drug Administration's approved labeling.

(B) The federal Food and Drug Administration's medical officers' and pharmacologists' reviews and the federal Food and Drug Administration's approved labeling.

(f) Departmental requests for information from persons filing drug petitions to which this section applies shall be specific and unambiguous and shall be made solely for the purpose of addressing the criteria utilized in accordance with subdivision (e).

(g) All published studies received by the department pursuant to a drug petition prior to the close of the public regulatory hearing record shall be accepted and considered by the department.

(h) Whenever the director decides to reject a petition to add a drug product to, or delete a drug product from, the formulary, the director shall notify the petitioner directly and in writing indicating the reason and specifying the criteria utilized in reaching the decision.

(i) The department shall accept a petition for a drug that has been rejected by the director upon the submission of another complete petition containing substantial new information that addresses the reason or reasons for rejection stated by the director pursuant to subdivision (h). Any petition accepted pursuant to this subdivision shall be processed in accordance with subdivision (c), or Section 14105.9, whichever is applicable.

(j) This section shall become operative on January 1, 1993.

Section 14105.405 is added to the Welfare and Institutions Code, to read:

14105.405. (a) (1) A Medi-Cal beneficiary, within 90 days of receipt of the director's notice to beneficiaries pursuant to subdivision (g) of Section 14105.33, informing them of the decision to delete or suspend a drug from the list of contract drugs, may request a fair hearing pursuant to Chapter 7 (commencing with Section 10950) of Part 2.

(b) (2) A beneficiary filing a fair hearing request regarding the deletion or suspension of a drug from the formulary shall be granted a treatment authorization request for that drug until a final decision is adopted by the director. Should the beneficiary seek judicial review of the director's decision, a treatment authorization request shall be granted for that drug until a final decision is issued by the court.

(c) (1) A Medi-Cal beneficiary, within one year of the directors' decision pursuant to Section 10959, may file a petition with the superior court, under the provisions of Section 1094.5 of the Code of Civil Procedure, praying for a review of both the legal and factual basis for the director's decision.

(2) The director shall be the sole respondent in these proceedings.

(d) Any Medi-Cal beneficiary injured as a result of being denied a drug which is determined to be medically necessary may sue for injunctive or declaratory relief to review the director's decision to delete or suspend a drug from the list of contract drugs.

(e) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.406 is added to the Welfare and Institutions Code, to read:

14105.406. The director shall, in considering suspension or deletion of drugs from the list of contract drugs, ensure that the department has the ability to process drug treatment authorization requests (TARs) without substantial degradation of the level of service, including response time, to providers which was in effect July 1, 1990.

In considering suspension or deletion of drugs, the director shall seek the advice of the Chief of the Field Services Branch and the Medi-Cal Contract Drug Advisory Committee.

If the treatment authorization request reports provided in subdivision (b) of Section 14105.42 indicate a substantial degradation in the level of service, including response time, for processing TARs, the director shall within 60 days, hold a public hearing on the functioning of the TAR system.

Subsequent to the hearing, the director shall consult with at least two members of each group represented on the Medi-Cal Contract Drug Advisory Committee as provided in subdivision (b) of Section 14105.4 and take appropriate action to remedy the problem areas discussed in the report and in the public hearing.

Based upon the information gathered as a result of the reports and public hearing referred to above, and in consultation with the Medi-Cal Contract Drug Advisory Committee, the director may add drugs which previously had been suspended or deleted to the list of contract drugs.

Section 14105.41 of the Welfare and Institutions Code is repealed.

Section 14105.41 is added to the Welfare and Institutions Code, to read:

14105.41. (a) For the purpose of adding drugs to, or deleting drugs from, the Medi-Cal drug formulary as described in Section 14105.4, whether pursuant to a petition or by the department independent of a petition, all of the requirements of the Administrative Procedure Act contained in Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code shall be applicable except that the requirements of subdivision (a) of Section 11347.1 and subdivision (b) of Section 11346.7 of the Government Code shall be deemed to have been complied with if the department does all of the following:

(1) Upon receipt of a petition requesting the addition of a drug to, or the deletion of a drug from, the Medi-Cal drug formulary, the department shall notify the petitioner directly and in writing of the receipt of the petition and shall, within 30 days, either return the petition as incomplete or schedule the petition for public hearing, unless the public hearing is not required pursuant to Section 14105.9.

(2) Notifies each petitioner directly and in writing of its decision regarding the addition of a drug product to, or deletion of a drug product from, the formulary and shall state the reason or reasons for its decision and the specific regulatory criteria that are the basis of the department's decision.

(3) Prepares and submits to the Office of Administrative Law with the adopted regulation all of the following for each drug which the

department has decided to add to, or delete from, the Medi-Cal drug formulary:

(A) A brief summary of the comments submitted. For the purpose of this section, "comments" shall mean the major points raised in testimony which specifically address the regulatory criteria upon which the department is authorized, pursuant to subdivision (e) of Section 14105.4, to bsse a decision to add or delete a drug from the formulary.

(B) The recommendation of the Medical Therapeutic and Drug Advisory Committee.

(C) The decision of the department.

(D) A statement of the reason and the specific regulatory criteria that are the basis of the department's decision.

(b) Any additional information provided to the department during the posting of revisions to the proposed regulation shall be responded to by the department directly and in writing to the originator. That response shall notify the originator whether the additional information has resulted in a changed decision.

(c) For the purpose of review by the court, if any, and review snd approval by the Office of Administrative Law of changes to the Medi-Cal drug formulary adopted by the department, each drug added to, or deleted from, the formulary shall be considered to be a separate regulation and shall be severable from all other additions or deletions of drugs contained in the rulemaking file.

(d) This section shall be applicable to any Medi-Cal drug formulsry regulation package filed with the Office of Administrative Law after January 1, 1986.

(e) This section shall become operative on January 1, 1993.

Section 14105.41 of the Welfare and Institutions Code is repealed.

Section 14105.41 is added to the Welfare and Institutions Code, to read:

14105.41. (a) Moneys accruing to the department from contracts executed pursuant to Section 14105.33 shall be deposited in the Health Care Deposit Fund, and shall be subject to appropriation by the Legislature.

(b) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a lster enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.42 of the Welfare and Institutions Code is repealed.

Section 14105.42 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.42. (a) The department shall report to the Legislature after the first three major therapeutic categories have been reviewed and contracts executed. The report shall include the estimated savings, number of manufacturers entering negotiations, number of contracts executed, number of drugs added and deleted, and impact on Medi-Cal beneficiaries and providers.

(b) The department shall provide the following data to the Legislature and to the Auditor General by January 1, 1991, and every six months thereafter:

(1) The number of drug treatment authorization request (TAR) received by facsimile, by secondary answering system and in person for each therapeutic category.

(2) The number of drug TARS requested, approved, denied, and returned.

(3) The length of time between the TAR request and the decision, specified by type of communication such as telephone or facsimile if available.

(4) For denied TARS, the number of fair hearings requested, approved, denied and pending.

(5) The numbers of providers who were unable to submit a request or made multiple attempts because of faulty or unavailable lines of communication, if available.

(6) The numbers of complaints made by beneficiaries and providers relating to difficulty or inability to obtain a TAR response.

(7) The status of the enhancements to the TAR process specified in the section.

(8) The number of calls on the TAR line which are not getting through.

(c) The Auditor General shall prepare a report by February 1, 1991, and every 6 months thereafter providing a summary and analysis of the data specified in subdivision (b), a comparative analysis of changes in the TAR process using June 1, 1990, as a base. The analysis shall include a measure of increased or decreased ability to contact the department and receive a response in a shorter or greater period of time.

(d) The department shall report to the Legislature, through the annual budget process, on the cost-effectiveness of contracts executed pursuant to Section 14105.33.

(e) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.42 is added to the Welfare and Institutions Code, to read:

14105.42. The provisions of Sections 14105.4 to 14105.41, inclusive, and Section 14105.65 shall not preclude the department from taking emergency regulatory action as it deems appropriate.

This section shall become operative on January 1, 1993.

Section 14105.43 of the Welfare and Institutions Code is amended to read:

14105.43. (a) Notwithstanding other provisions of this chapter, any drug which is approved by the United States Food and Drug Administration for use in the treatment of acquired immune deficiency syndrome (AIDS) or an AIDS-related condition shall be deemed to be approved for addition to the Medi-Cal list of contract drugs only for the purpose of treating AIDS or an AIDS-related condition, for the period prior to the completion of the procedures established pursuant to Section 14105.33.

(b) Any drug deemed to be approved pursuant to subdivision (a) shall be immediately added to the Medi-Cal list of contract drugs, and shall be exempt from the contract requirements of Section 14105.33.

(c) If it is determined pursuant to subdivision (d) of Section 14105.39 that a drug to which subdivision (a) applies should not be placed on the Medi-Cal list of contract drugs, that drug shall no longer be deemed to be approved for addition to the list of contract drugs pursuant to subdivision (a).

Section 14105.45 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.45. The department shall establish a list of Maximum Allowable Ingredient Costs (MAIC) for drugs, which shall be published in provider bulletins. On the effective date of this section, MAICS listed in Title 22 of the California Code of Regulations shall be included in the list of MAICS. MAICs shall no longer be listed in regulations. The department shall repeal Section 51513.3 of Title 22 of the California Code of Regulations.

(b) The department shall establish additional MAICS in accordance with all of the following:

(1) The department shall base sn MAIC on a reference drug brand which is therapeutically equivalent to the innovator brand, and which is manufactured by a company with production capability to meet the statewide needs of the Medi-Cal program for that drug.

(2) The decision regarding therapeutic equivalency shall be based on the federal Food and Drug Administration determinations. For antacid drugs, therapeutic equivalency shall be determined by the department based on review of in vitro scientific data.

(3) The department shall request information from drug manufacturers regarding the availability of their products throughout the state to outpatient pharmacies through the usual and customary distribution channels in sufficient quantities to meet the needs of the Medi-Cal program.

(4) The department shall notify Medi-Cal providers at least 30 days prior to the effective date of an MAIC.

(c) Notwithstanding the provisions of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, actions under this section shall not be subject to the Administrative Procedure Act, or to the review and approval of the Office of Administrative Law.

Section 14105.7 of the Welfare and Institutions Code is amended to read:

14105.7. (a) In order to fairly reimburse pharmacies for the furnishing of prescription drugs to Medi-Cal beneficiaries, the director shall update allowable drug product prices no less often than every 30 days. The update shall include any prior change in drug product price of which the director has received notice. Notice to the director shall include, but not be limited to, publication of the price change in the supplier's catalog or supplement or in nationally distributed drug price reference guides.

(b) No regulation reducing allowable drug product cost reimbursement or removing a drug from the Medi-Cal list of contract drugs shall be operative until at least 30 days after eligible pharmacies have been mailed a notice of the reimbursement limitation by the department or the fiscal intermediary.

(c) The director shall limit the rate of payment for the professional fee portion of prescription services rendered under this chapter pursuant to Section 4229.5 of the Business and Professions Code or Section 11201 of the Health and Safety Code and the professional fee portion of prescription services rendered as a refill immediately subsequent to such prescription to ensure that the total professional fee paid for the two services does not exceed the professional fee paid for the same prescription refill when provided as a routine service.

Section 14105.91 of the Welfare and Institutions Code is repealed.

Section 14105.91 is added to the Welfare and Institutions Code, to read:

14105.91. The department may add a drug to the formulary which is a different dosage form, or strength of a drug product which is listed in the formulary without review by the Medical Therapeutics and Drug Advisory Committee and the addition shall be deemed to comply with the requirements of the California Administrative Procedures Act.

This section shall become operative on January 1, 1993.

Section 14105.915 is added to the Welfare and Institutions, to read:

14105.915. The department may remove any drug from the formulary at the expiration of the contract term or when the contract between the department and the manufacturer of that drug is terminated.

This section shall become operative on January 1, 1993.

Section 14105.916 is added to the Welfare and Institutions Code, to read:

14105.916. Notwithstanding any other provision of law, on and after January 1, 1993, drugs on the Medi-Cal list of contract drugs shall become the Medi-Cal drug formulary.

Section 14105.92 of the Welfare and Institutions Code is amended to read:

14105.92. (a) Notwithstanding any other provision of law, pentoxifylline tablets shall, no later than July 1, 1990, be added to the Medi-Cal list of contract drugs for treatment of persons diagnosed as having both diabetes and intermittent claudication.

(b) For indications other than intermittent claudication, pentoxifylline may only be available upon approval of a prior authorization request submitted by a qualified provider, unless other indications are authorized pursuant to regulations adopted by the department.

(c) Pentoxifylline tablets shall be exempt from the contract requirements of Section 14105.33.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14132 of the Welfare and Institutions Code is amended to read:

(a) through (c) unchanged.

(d) Purchase of prescribed drugs is covered subject to the Medi-Cal list of contract drugs and utilization controls.

(e) through (z) unchanged.

Section 14132d of the Welfare and Institutions Code, as added by Assembly Bill 4104 of the 1989-90 Regular Session, is amended to read:

14132d. Any purchase of prescribed drugs is covered under this chapter subject to the Medi-Cal list of contract drugs and utilization controls.

Section 14133.2 of the Welfare and Institutions Code is amended to read:

14133.2. The director shall include in the Medi-Cal list of contract drugs any drug approved for the treatment of cancer by the Federal Food and Drug Administration. These drugs shall be exempt from the contract requirements of Section 14105.33.

Article 5.5 (commencing with Section 14180) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code is repealed.

The State Department of Health Services may adopt emergency regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, to implement Sections 13 to 28, inclusive, and Sections 30 to 33, inclusive, of this act. The adoption of those regulations shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, or safety. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, emergency regulations adopted by the department in order to implement Sections 13 to 28, inclusive, and Sections 30 to 33, inclusive, of this act shall not be subject to the review and approval of the Office of Administrative Law. These regulations shall become effective immediately upon filing with the Secretary of State.

Section 34 of Assembly Bill 3573 of the 1989-90 Regular Session is amended to read:

Sec. 34. (a) Except as provided in subdivision (b), the department shall adopt emergency regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code within 120 days of the enactment of this act to implement Section 33 of this act. The adoption of regulations pursuant to this section in order to implement Section 33 of this act shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, or safety. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, emergency regulations adopted pursuant to this section within 120 days of the enactment of this act shall not be subject to the review and approval of the Office of Administrative Law. The regulations shall become effective immediately upon filing with the Secretary of State. The regulations shall not remain in effect more than 120 days unless the adopting agency complies with all of the provisions of Chapter 3.5 (commencing with Section 11340) as required by subdivision (e) of Section 11346.1 of the Government Code.

(b) The dispensing or markup fee, which is a factor in reimbursement for incontinence medical supplies as described in Section 14125 of the Welfare and Institutions Code, shall not be changed or adopted pursuant to the authorization to adopt emergency regulations set forth in subdivision (a).

PREPARED STATEMENT OF SENATOR DAVID PRYOR

Good Morning. Mr. Chairman, I want to thank you and Chairman Bentsen for calling this important hearing to discuss skyrocketing prescription drug prices and how they have affected our State Medicaid programs. As you will hear today from many of our witnesses, Medicaid has received a second class deal from our nation's drug manufacturers. This morning's hearing will give us an excellent opportunity to evaluate plans that attempt to change this unacceptable situation.

Year in and year out, the drug companies have refused to give our $9 billion dollar Medicaid prescription drug programs the 40 to 70 percent discounts on drugs that they routinely offer to other much smaller purchasers of their products. By not having access to these discounts, the Medicaid program has shouldered the unyielding and entire weight of prescription drug price inflation.

As our constituents tell us every time they get the chance, this is no light burden. In fact, as the chart I have brought with me demonstrates, over the last ten years, consumer prices increased 58 percent while prescription drug prices rose by a staggering 152 percent. These unyielding and unfair prices have forced States to slash Medicaid recipients' benefits and pharmacy and other health care provider's reimbursement rates. In essence, the drug manufacturers are holding our States hostage to their price increases.

To liberate our States from this unbearable situation, I have proposed two legislative approaches that will assure fair prices and substantial savings for Medicaid. The first bill, S. 2605, saves money by requiring manufacturers to bargain over the value of their drugs.

By the drug manufacturers' reaction to my bill, you would think that bargaining over the value of their drugs was something they had never seen or done before. In fact, manufacturers engage in this type of bargaining day in and day out with the nation's best hospitals and HMOs. In fact, one such HMO—Kaiser Permanente—serves over 400 Senate employees on an inpatient and outpatient basis. As far as I know, none of them—or PMA for that matter—have described this HMO as second class medicine.

For the record, I would like to submit a list of over 25 national organizations who support S. 2605. I also would like to submit an Aging Committee staff briefing paper that documents how these same negotiating systems are being used throughout the country,, including in such respected institutions as the Harvard Community Health Plan, the Cleveland Clinic, and the Mayo Clinic.

The drug industry, by their own admission, is afraid of the enactment of S. 2605 because private insurors might use the same approach. Very recently, in an attempt to make certain this does not happen, a number of companies shocked the industry by offering their own proposals that eliminate the negotiating methods outlined in S. 2005. In most of these plans, the manufacturers promise to give Medicaid their best or something close to their best prices. I have commended these companies for trying. Unfortunately, CBO and OMB don't cost out promises and have informed me that it is highly unlikely that the proposals will produce significant savings.

Under their plans, drug manufacturers would have free reign to eliminate or significantly reduce discounts. Mr. Chairman, that's like putting a fox in charge of the hen house. We need only look at how the drug manufacturers tried to renege on their voluntary promise to give rebates to the Women, Infants and Children (WIC) program for cans of infant formula.

In response to the industry alternatives, I introduced a second bill this past Wednesday. The Medicaid Anti-Discriminatory Drug Price arid Patient Benefit Restoration Act of 1990 (S. 3029), builds on the plans that the manufacturers have proposed. The main difference between my plan and their plans is that, by indexing the manufacturers current best prices to the rate of inflation, mine assures significant savings for Medicaid. Already, S. 3029 has been endorsed by Families USA, the Children's Defense Fund, the National Council of Senior Citizens, AARP, the American Cancer Society, the National Association of Retail Druggists, and the American Pharmaceutical Association.

Mr. Chairman, we have all seen the extraordinarily well-financed PMA and their member drug companies roll onto Capitol hill in an attempt to defeat my legislation. Frankly, I don't mind a good fight. It saddens me, however, to know that the same vulnerable people paying such high drug prices already will be forced to pay even higher prices to underwrite PMA's armies of lobbyists and P.R. firms.

Despite the industry's intense campaign, I believe that we are on the verge of enacting a Federal Medicaid drug cost reduction law. This is because the industry's extraordinarily talented and expensive lobbyists have not been able to adequately respond to the simple question why, in an era of great fiscal and social needs, the poverty program for the poor should be forced to pay unjustifiably high and inflated prices for drugs.

Mr Chairman, you will hear a lot of arguments against my two bills. Some manufacturers will argue that it is unfair for them to bear the brunt of cost containment in Medicaid because only 6 cents of every Medicaid dollar is spent on drugs. Following that logic, we should also forget finding a better way to purchase a $600 toilet seat simply because it represents one thousandth of one percent of the Pentagon budget.

The fact is, we spend well over half of the Medicaid drug budget on brand name drug products. In some states, it is as high as 90%! If Medicaid received discounts of just 20 to 30% off-these products, we could save anywhere from $200 to 300 million a year. That might not mean much to the drug industry, but it sure would make a difference to Medicaid and the poor people it serves.

Some within the industry argue that I should not be critical of their profit margins. They say they have already given their fair share. I find this astonishing. Year after year the brand name prescription drug industry leads all industries in record profits across all categories. As this chart behind me shows, drug manufacturers are the most profitable of any industry in the U.S. The yellow lines represent the median profitability of the average Fortune 500 company in 1989. The blue lines represent the second highest-profit-making industry in the nation. The red lines, Mr. Chairman, show that the manufacturers top the charts on all measures of profits.

Some will say that these profits are needed to fund the tremendous costs of R&D that the industry has to bear. I say that their inflated prices go to pay for the tremendous cost of marketing drugs that have little or no therapeutic advance over drugs in the market. Some recently released information concluded that for every $1 they invest in R&D, many manufacturers spend $3.50 on marketing and advertising. What amazes me most, Mr. Chairman, even if you assume the enactment of either one of my two bills, Wall Street is characterizing the impact of such savings from the drug industry coffers as "trivial."

Finally, some manufacturers will argue that Federal legislation in this area is not needed because "market forces" are today encouraging drug companies to offer rebates or discounts to state Medicaid programs. Do they think that this Congress will believe for one second that it is market forces that are responsible for these very recent movements in the industry?

I submit that it is the threat of—and hope to avoid—Federal legislation that has some drug companies converging on our State capitols to sign agreements. What guarantee do we have that the discounts now given will not he eliminated or significantly reduced without Federal legislation? Absolutely none. What guarantee do we have that all companies will sign agreements with all states, regardless of whether they are a small or large state? Again, absolutely none. It will only be through Federal legislation that we will assure savings for Medicaid.

Mr. Chairman, in an era of fiscal constraints, we may need to reduce certain entitlement programs. There is no justifiable way we can ask Medicare beneficiaries, physicians, hospitals, or pharmacists to do more, while we leave the drug companies untouched.

Let me conclude by saying that I am eager to hear from and question the many witnesses we have here today. Mr. Chairman, let me once again remind my colleagues that regardless of the distractions that the drug manufacturers throw our way, we must continue to focus on our goal: finding the best way for the Medicaid program to get a better deal on the tremendous amount of drugs it buys each year. I am proud to say that through our efforts, the days of drug manufacturers giving the Medicaid program "second class treatment" are quickly coming to a close.

Attachments.

Chairman Predicts Congress on the Verge of Enacting Medicaid Drug Cost Reduction Law

"DAYS OF SECOND CLASS TREATMENT FROM MANUFACTURERS COMING TO A CLOSE," PRYOR TELLS FINANCE SUBCOMMITTEE

WASHINGTON—The Medicaid program has shouldered "unyielding and unfair" prescription drug prices while huge discounts are offered to other purchasers, and it's time to find a better deal, Chairman David Pryor (D-ARK) said during testimony to a Finance Subcommittee today.

The Subcommittee on Health for Families and the Uninsured considered two bills by Pryor, a proposal by the Health Care Financing Administration, and several-drug industry plans to reduce the cost of Medicaid prescription drugs. The Medicaid program, serving-the nation's poor, pays about $9 billion per year for prescription drugs

"You will hear a lot of arguments against my two bills," Pryor told Subcommittee members. "Some manufacturers will argue that it's unfair for them to bear the brunt of cost containment in Medicaid because only 6 cents of every Medicaid dollar is spent on drugs. Following that logic, we should also forget finding a better way to purchase a $600 toilet seat simply because it represents one thousandth of one percent of the Pentagon budget."

"We spend well over half of the Medicaid drug budget on brand name drug products," Pryor continued. "In some states, it is as high as 90%! If Medicaid receives discounts of just 20 to 30% off these products, we could save anywhere from $200 to $300 million a year. That might not mean much to the drug industry, hut it sure would make a difference to Medicaid and the poor people it serves."

Pryor also released a Committee briefing paper on therapeutic drug equivalence, and manufacturer bargaining over the value of drugs. That concept is the basis of Pryor's first bill (S. 2605) to assure fair prices and substantial savings for Medicaid. The paper documents how these same negotiating systems are being used successfully throughout the country.

"The recent generalization of therapeutic formularies as 'second class health care' is clearly inappropriate," the report states. "Sixty two percent of the nation's largest Health Maintenance Organizations (HMOs) employ therapeutic formularies to control costs and improve prescribing of drugs in inpatient and outpatient settings."

Pryor's second bill (S. 3029) indexes the manufacturer's current best prices to the inflation rate.

THERAPEUTIC DRUG FORMULARIES AND THERAPEUTIC EQUIVALENCE OF PRESCRIPTION DRUGS

[A Briefing Paper prepared by the Majority Staff of the U.S. Senate Special Committee on Aging, September 1990]

INTRODUCTION

In acknowledgment of the recent surge of interest in therapeutic formularies, Senator Pryor, Chairman of the Special Committee on Aging and sponsor of S. 2605 (the pharmaceuticals Access and Prudent purchasing Act of 1990 (PAPPA)), instructed Committee staff to prepare a written overview of current policies and practices of health care providers who use therapeutic formularies.

This briefing memo is meant to bring to light facts that have been obscured during the debate over cost-containment in Medicaid's prescription drug program. An example of one particularly specious assertion that has gained some currency on Capitol Hill in recent months is the characterization of therapeutic formularies as "second class health care." This generalization is clearly inappropriate. The American Society of Hospital pharmacists' 1990 national survey of hospital pharmacy departments found fully 58% of U.S. hospitals reported having "a well controlled (closed) formulary with almost no duplication of generic equivalents and minimal duplication of therapeutically equivalent drug products."

Similarly, 62% of the nation's 188 largest health maintenance organizations employ therapeutic formularies to control costs and improve prescribing of drugs in inpatient and outpatient settings, with an additional 11% of HMOs in the process of implementing a formulary. According to the survey authors at Scott-Levin Associates, last year a total of 20 million Americans belonged to health care programs that exercise "true formulary controls," under which doctors' prescribing is closely monitored. Physician acceptance of the prescribing preferences set forth by these health plans may be seen in the large number of doctors who continue to follow the plan prescribing guidelines for their non-plan patients. Scott-Levin estimated "an equal number of Americans—20 million now receives the identical prescriptions, even though they do not belong to the managed health care programs that created and enforce the prescription controls."

Some of the prestigious health care providers who employ a therapeutic formulary for either or both inpatients and outpatients include (see Part Two of this memo for a more complete listing):

Geisinger Medical Clinic (Danville, PA)—
Harvard Community Health Plan
National Naval Medical Center (Bethesda)

Scott and White Memorial Hospital (Waco, TX)
The Cleveland Clinic Hospital
The Mayo Clinic
The Robert Wood Johnson University Hospital
Thomas Jefferson University Hospital (Philadelphia)
Walter Reed Army Medical Center (Washington, DC)

This memo is divided into two parts. The first part is devoted to a discussion of the unique role of therapeutic formularies in the medical community. The second section is presented under the assumption that the best way to convey the judgments of health care professionals serving on "formulary committees" is to let them speak for themselves. Accordingly, Part Two of this memo consists of excerpts of internal documents and publications representing the judgments of Pharmacy and Therapeutics (P&T) Committees in hospitals, outpatient clinics, and managed care settings.

PART ONE: THE THERAPEUTIC FORMULARY PROCESS IN THE CONTEXT OF HEALTH CARE TECHNOLOGY ASSESSMENT

The public hearings of the Special Committee on Aging concerning prescription drug prices, held in July and November 1989, and the subsequent introduction of S. 2605 (the Pharmaceuticals Access and Prudent Purchasing Act of 1990, or "PAPPA") on May 10, 1990, have stimulated great interest among health care policymakers in therapeutic formularies as a means of negotiating favorable prescription drug prices; Senator Pryor's proposal to build on the strengths of the formulary process is consistent with congressional action in November 1989 to establish the Agency for Health Care Policy and Research (AHCPR). According to Senator George Mitchell, author of the Senate bill that created AHCPR,

> "Although the ingenuity of our medical scientists renders our future medical capability virtually limitless, the rapid development of medical procedures has not been accompanied by adequate efforts to prove their effectiveness, appropriateness and their relative value and cost. These factors may contribute to the substantial amount of geographical variation that exists in the type and number of services provided to patients with the same condition. . . . The variation in practice methods does not mean that physicians are cavalier or that they use poor judgment when they treat their patients. Rather, there is evidence that often they simply must make decisions based on inadequate information. [Floor statement of Senator Mitchell, April 5, 1989]

Sennator Mitchell's assessment applies to pharmaceutical therapies, as well as many other medical and surgical interventions. While prescription drugs must be demonstrated safe and effective to be marketed in the United States, the FDA does not condition its approval of new drugs on a comparison of their new therapeutic contribution (if any) to existing therapies. The average physician has little time and opportunity to unearth even existing published information regarding the "appropriateness and . . . relative value and cost" of pharmaceuticals. In fact, the American College of Physicians has recently stated of the typical medical school curriculum

> "[v]irtually all formal pharmacologic education presently occurs in the second year of medical school, before significant exposure to clinical medicine. In this context, students are taught about drugs that are used to treat diseases with which they have only passing acquaintance, and have never actually seen in clinical situations. This often amounts to giving students solutions to problems they have yet to recognize exist. . . . After the completion of formal medical school and house officer training, there is no systematic exposure to intelligent, informative, and unbiased assessments of drug therapy. . . . The entire process can be characterized as largely random, incomplete, and subject to distortion." [American College of Physicians, Health and Public Policy Committee, in *Annals of Internal Medicine,* 1988.]

To aid physicians contend with the absence or inaccessibility of objective comparative information on therapeutic options, Congress has explicitly authorized the drafting of treatment guidelines by experts funded under AHCPR programs. In addition, in recognition that reimbursement policy should reflect the best medical practice, Congress mandated that the new Agency:

> "make recommendations to the [HHS] Secretary with respect to whether specific health care technologies should be reimbursable under federally fi-

> nanced health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made." (Section 6103(a) of the Omnibus Budget Reconciliation Act; of 1989)

The new policy embodied in this legislation is built on the work of a non-governmental entity, the Maine Medical Assessment Foundation's patient outcomes research. Similarly, S. 2605 is built on the work of Pharmacy and Therapeutics ("P&T") Committees at scores of individual hospitals, outpatient clinics, and health maintenance organizations surveyed by the staff of the Aging Committee. These providers have for many years studied patient outcomes studies for clues to more appropriate drug therapy. They have published therapeutic formularies to guide physicians to safe and cost-effective treatment options amongst the bewildering array of prescription products on the market.

The formulary process in the United States has evolved over two hundred years into a widely-accepted multidisciplinary collaboration by health professionals. It is deserving of congressional attention if only because it represents a unique voluntary effort to assess -alternative health technologies and integrate cost considerations with patient outcomes data from clinical studies.

THE THERAPEUTIC FORMULARY PROCESS

A formulary is the end product of a process of evaluation and comparison of drug therapies, resulting in a list of preferred products, selected for their therapeutic attributes and/or economic advantages. Drug products may be preferred by clinicians for (1) their unique medicinal advantages over other products used for the same purpose ("drugs of choice"), and (2) their economic advantage over other products which have been judged to be of equivalent therapeutic value.

A formulary would be impossible if the differences between drugs were all clinically significant. There is little doubt that some drags are clearly superior to others in treating a given condition. But it is also true that some drugs are clinically equivalent in terms of safety and efficacy for a large proportion of the population.

This is not a theory, but a widely-accepted reality. For years, pharmacological experts at university teaching hospitals and clinics, as well as many Health Maintenance Organizations (HMOs), have acted in the knowledge that some drugs, though different chemically, are equally safe and effective in diagnosing, preventing, and treating most patients' ailments and conditions. In December 1983 the American Medical Association and the American Pharmaceutical Association, the two largest organizations representing the professions of medicine and pharmacy, agreed to define as a "therapeutic alternate" any drug

> "product that contains a different therapeutic moiety than the drug in question but is of the same pharmacological or therapeutic class and can be expected to have a similar therapeutic effect when administered to patients in a therapeutically equivalent dosage."

The starting point of any therapeutic formulary, therefore, is assessment of the relative safety and efficacy of drug products, followed by identification of which drug products are superior and which are therapeutic alternates. Products found to be superior are listed in the formulary. In a typical formulary, one or more products from each group of therapeutic alternates are then selected as "preferred," usually on the basis of cost.

Gary Smith, director of the Drug Information Center at the University of Arizona Medical Center, describes the formulary process this way:

> "If, after consideration of both safety and efficacy, more than one therapeutic choice is available, using the drug which is the least expensive to supply and monitor can benefit the patient directly through reduced charges, and indirectly by allowing . . . resources to be devoted to other areas of patient care."

Another excellent description of the advantages of a therapeutic formulary may be found in the introduction to the Drug Formulary for the Kaiser Permanente (Mid-Atlantic Region) health plan, of which some 400 Senate employees are presently members:

> "*The Formulary is intended to enhance to quality of patient care* by . . . providing requisite information for the optimal use of drugs, limiting the availability of unsafe, 'less than effective' and 'ineffective' drugs and limiting the use of drugs with a high potential for toxicity or abuse.

> *"The Formulary is intended to reduce costs by educating providers* on the relative economics of various drug therapies, promoting the use of effective but less costly therapeutic equivalents, reducing the number of therapeutically redundant drugs, maximizing leverage through the drug purchasing and bid process, promoting the use of standard package sizes to improve pharmacy productivity and optimizing pharmacy management of drug inventories." [emphasis supplied]

But however much deliberation is given to its development, a formulary remains only a list of preferred drugs, not a policy etched in stone, unalterable and impersonal. All of the formularies examined by staff of the Special Committee on Aging provided for an individual patient's physician to "override" the preferred product when a physician attests to the medical necessity of doing so.

The importance of a physician override was described by the Director of Pharmacy Services for The University Hospital at Boston University Medical Center in the September 1989 issue of the American Journal of Hospital Therapy. He advocated a formulary process "which allows for the occasional exception to the therapeutic equivalence rule," because it offers "cost avoidance when a group of drugs is therapeutically equivalent in most, but not all, patients." According to this article, therapeutic equivalence policies that allow for exceptions "cannot be rejected simply because of a lack of therapeutic equivalence in a few patients. Even when the exceptions total 25% of patients, a policy that allows the use of a lower-cost agent in the other 75% can result in substantial cost avoidance." The University Hospital successfully implemented such a policy for certain antibiotics and the anti-ulcer agents known as "H_2 Antagonists, with excellent physician acceptance of and compliance with the new policy.

In summary, a decision as to which drug products are therapeutic alternates is reached after careful examination of clinical data, based upon patient outcome studies. It is a judgment for a population of patients, but is flexible to the needs of each individual.

PART TWO: EXAMPLES OF PHARMACY & THERAPEUTICS COMMITTEE JUDGMENTS OF THERAPEUTIC EQUIVALENCE

In addition to the hospitals, HMOs and State Medicaid plans surveyed by Committee staff, the following hospitals, clinics and managed care organizations with a well-developed therapeutic formulary process served as models for S. 2605 and its reform of current Medicaid formulary practices:

Albany Medical Center (New York)
Barnes Hospital, Washington University Med Ctr (St. Louis)
Carle Foundation Hospital (Urbana, IL)
Geisinger Medical Clinic (Danville, PA)
Group Health of Puget Sound (Seattle)
Hamot Medical Center (Erie, PA)
Harvard Community Health Plan
Kaiser Permanente—Mid Atlantic Region
Kaiser Permanente—Northwest
Mayo Clinic
Medical Center of the University of California, San Francisco
Medical College of Virginia
National Naval Medical Center (Bethesda, MD)
Ohio State University Hospital
PARTNERS National Health Plans
Scott and White Memorial Hospital (Waco, TX)
The University Hospital of Arkansas
The Robert Wood Johnson University Hospital
The Cleveland Clinic Hospital
Thomas Jefferson University Hospital
University of Alabama Hospital
University of Arizona Medical Center
University of California, San Diego Medical Center
University Hospital at Boston University
University Hospital of Jacksonville, University of Florida
University of Illinois Hospital
University of Massachusetts Medical Center
University of North Carolina Memorial Hospital
Walter Reed Army Medical Center (Washington, DC)
Yale-New Haven Hospital.

The following quotations, organized chronologically within broad drug classifications, are provided to illustrate and summarize actual judgments of therapeutic equivalence by physicians, pharmacists, and other health professionals working in hospitals, HMOs, and outpatient clinics. Quotations were excerpted from Pharmacy and Therapeutics Committees' reviews of such outcome studies and peer-reviewed scientific literature.

These excerpts are presented (1) to provide concrete examples of therapeutic alternates identified by practicing physicians and pharmacists, (2) to debunk groundless generalizations about formularies as "second-class health care", and (3) as an exemplar for policymakers interested in technology assessment as a process that can guide public and private health insurers to make more appropriate reimbursement decisions.

Anti-hypertensives (high blood pressure medications)

(Note: Antihypertensives account for about 9–16% of Medicaid drug expenditures.)

- "Nicardipine [Cardene] appears to be effective in the treatment of both essential hypertension and angina. It offers no advantage over nifedipine [Procardia, Adalat], propranolol [Inderal] or hydrochlorothiazide [Esidrix, Oretic, others] in treating essential hypertension; it also has no advantages over verapamil [Calan, Isoptin], propranolol or nifedipine in treating angina. Since the cost of nicardipine is either equal to or more expensive than nifedipine, we do not recommend adding nicardipine to the formulary at the present time. —Univ of Arizona Medical Center Drug Review, January, 1990.
- "Clinical trials comparing the efficacy of terazosin [Hytrin) and prazosin [Minipress) reveal no significant differences between the two agents. Terazosin once-daily dosing which may enhance patient compliance is the only benefit to terazosin. Prazosin is significantly less expensive than terazosin when comparing usual daily dosage regimens. For these reasons, the Department of Pharmacy recommends that terazosin not be added to the Formulary of Accepted Drugs."—Ohio State University Hospital, terazosin drug review, May, 1988.
- "In summary, lisinopril [Zestril] has about equal efficacy in controlling blood pressure as metoprolol [Lopressor], atenolol [Tenormin], and nifedipine (Procardia] as single agent therapy."—Veterans Administration Medical Center (VAMC) Tucson, AZ. Pharmacy Newsletter, August, 1988.
- "Despite the widespread use of diltiazem (Cardizem] at this Medical Center, little differences exist between these two drugs [verapamil and diltiazem]. . . Comparative trials in hypertensive and angina patients have shown that both drugs have comparable effects on heart rate, PR interval and blood pressure. . . Both verapamil [Calan) and diltiazem are equally effective to nifedipine [Procardia] and beta blockers in treating chronic stable angina. . . The side effects of verapamil and diltiazem are similar."—Veterans Administration Medical Center, Tucson, AZ. Pharmacy newsletter, September, 1988.

Antibiotics/Anti-infectives

- "Antibiotics account for approximately 12% of Stanford inpatient drug expenditures. In many cases, less expensive antibiotics may be as effective as newer, more costly agents."—Stanford Univ Hospital, Drug Information Service Newsletter, February, 1990.
- "The medical literature does not contain evidence of differences in clinical efficacy between the available IVIG (intravenous immunoglobulin) products . . . pharmaceutical and economic factors (including acquisition cost and manufacturer service policy) become important variables in the formulary decision process."—Geisinger Medical Clinic (Danville, PA) Drug Review, November 13, 1989.
- "For the vast majority of patients cefoxitin (Mefoxin) and cefotetan [Cefotan] should be equally efficacious. The decision [of which drug will be listed on the formulary] therefore may be made based oil cost."—Univ of Arizona Medical Center Drug Review, November 1989.
- "These recommendations [to leave tobramycin (Nebcin) and amikacin (Amikin) off the formulary] are based on the similar sensitivities and safety profile of gentamicin (Geramycin, G-Mycin, Jenamicin, others) versus tobramycin and the considerable cost savings possible with gentamicin use." Carle Clinic estimated that it could save $18,564 based on the previous year's usage. —Carle Foundation Hospital (Urbana, IL) Aminoglycoside Usage Evaluation, October 1989.
- "With the exception of cefotaxime for colorectal surgery, all of the anaerobic cephalosporins appear comparably effective and safe for surgical prophylaxis and selection should be made on the basis of cost."—Drug Information Bulletin, Univ of Alabama Hospital, September 1989.

- "University of Missouri Hospital and Clinics (UMHC) consultants agree that piperacillin (Pipracil) 4 g every 6 hours should be therapeutically equivalent to ticarcillin [Ticar] 3 g every 4 hours. Since piperacillin costs more than ticarcillin per gram, the savings derive from using fewer grams and fewer doses."—University of Missouri Hospital and Clinics Pharmacy Newsletter, July 19, 1989.
- ". . . the P and T Committee declared cefoxitin and cefotetan therapeutic equivalents."—Minutes of P and T Committee, Univ of Alabama Hospital, July 1989.
- "Cefazolin, cephalothin, and cephapirin are considered therapeutically equivalent at Y-NHH. The Pharmacy & Therapeutics Committee has promoted the use of cephalothin over cefazolin in the past because cephalothin's lower drug acquisition cost offset its disadvantage of more frequent dosing. However, recent decreases in drug acquisition cost now make it desirable to promote the use of cefazolin whenever a first generation cephalosporin is required."—Formulary Update, Yale-New Haven Hospital, October 1988.
- "Due to the lack of data to demonstrate a therapeutic, safety or financial advantage of cefixime [Suprax] over existing MCVH Formulary antibiotics [cefaclor and amoxicillin-clavulanate], the Drug Information Service, Department of Pharmacy Services, recommends *not* to add cefixime to the MCVH Formulary."—Medical College of Virginia Hospital Drug Review, October 19, 1988.
- "The hospital cost of tobramycin, on the other hand, is $4.78/80 mg vial compared to $.22/80 mg vial of gentamicin. While activity between these two agents differs for P. aeruginosa, it may not be significant enough to justify the cost of tobramycin for general use."—Ohio State Univ Hospital Pharmacy Bulletin, Fall, 1987.
- "The Pharmacy & Therapeutics Committee has ruled that cefoxitin (Mefoxin; Merck, Sharp, Dohme) and cefotetan (Cefotan; Stuart) are therapeutically equivalent cephalosporin antibiotics. This decision was based on a comparison of their *in vitro* antibacterial activity, clinical efficacy, and toxicity. Both of these drugs are particularly active against anaerobic bacteria. *** A competitive bid was issued to both companies, and cefotetan will become the Formulary anti-anaerobic cephalosporin on Tuesday, January 13, 1987. Patients receiving cefoxitin prior to this day will continue to receive cefoxitin until their therapy is completed. Physicians who write new orders for cefoxitin will be contacted and given information on the use of cefotetan."—Formulary Update, Yale-New Haven Hospital, December 1986.
- "In 1975, the Pharmacy and Therapeutics Committee of the Medical Board reviewed these 2 cephalosporins [cephadrine and cephalexin] extensively and concluded that they are therapeutically equivalent. A competitive bid in 1975 resulted in cephalexin being retained on the Formulary since that drug provided the lower cephalosporin cost. The Committee reaffirmed its position in May, 1977 and a June, 1977 bid resulted in a 33% lower cost for cephradine. Cephradine and cephalexin are remarkably similar in their chemical, pharmacological and pharmacokinetic properties."— Drugs In Patient Care, Yale-New Haven Hospital, Department of Pharmacy Services, July 1977.

Anti-Ulcer Drugs (H_2 Antagonists)

(Note: This class of drugs represents about 6–11% of Medicaid drug program expenditures.)

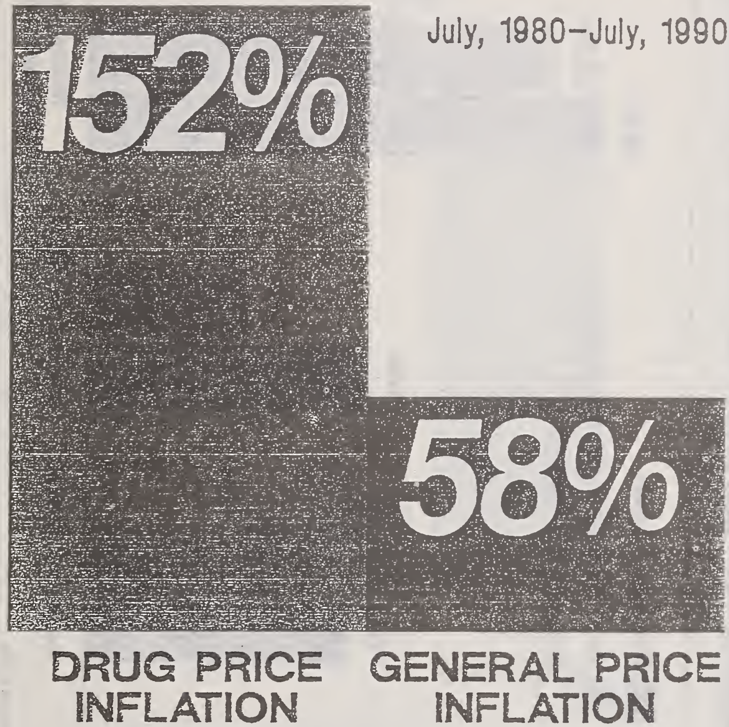
- The P and T "Committee did not feel famotidine had advantages over ranitidine, the current IV H_2 blocker on formulary. Famotidine is no more or less effective than any other H_2 blocker. Its rate of drug interactions is not significantly different from ranitidine."—P and T Minutes from VAMC Amarillo (TX), February 8, 1990.
- "The healing rates were essentially the same with cimetidine or ranitidine in patients treated for duodenal ulcer, gastric ulcer, reflux esophagitis, or acid-mediated dyspepsia. The differences in drug interaction profiles were not clinically significant."-Fresno (CA) Veterans Affairs Medical Center Newsletter, January 1990.
- "A literature review conducted by pharmacists at a 273 bed non-teaching community hospital showed that i.v. famotidine was as safe and effective as i.v. cimetidine or ranitidine . . . [t]he acceptance of a therapeutic interchange program for H_2 antagonists was excellent, and the projected savings are substantial."—*American Journal of Hospital Pharmacy.* 1990;47: 1547–51.
- ". . . the [Pharmacy and Therapeutics] committee approved a policy allowing for automatic substitution of ranitidine for famotidine (Pepcid) and cimetidine [Tagamet]. This decision was based on similar efficacy profiles of the drugs, reduced potential for drug-drug interactions and projected cost savings."—Univ of Massachusetts Medical Center Pharmacy Memo, December 14, 1989.

- "Studies show equal efficacy for famotidine [Pepcid] and ranitidine [Zantac] at reducing gastric acid secretion when properly dosed. On the basis of an evaluation of efficacy, safety, and cost, the Pharmacy and Therapeutics Committee has decided to make this change [to replace ranitidine with famotidine] in the formulary."—Univ of Arizona Medical Center Drug Therapy Highlights, November 1989.
- "Famotidine [Pepcid], ranitidine [Zantac), and cimetidine [Tagamet) appear to be equally effective in treating gastric and duodenal ulcers when adequate doses are administered."-Carle Foundation Hospital (Urbana, IL) Group Review of Parenteral H_2 antagonists, October 1989.
- "To ensure that the literature supported therapeutic equivalence (of raniditine and cimetidine], data derived from more than 50 articles comparing the three commercially available H_2 Antagonists (cimetidine, ranitidine, and famotidine] were prepared by the pharmacy's clinical coordinator. . . . The P&T Committee unanimously approved the therapeutic equivalence policy for cimetidine and ranitidine, but not for famotidine (until more experience could be gained with the drug). . . . Before the therapeutic equivalence decision for histamine H_2 receptor antagonists, ranitidine accounted for about 84% of the hospital's injectable H_2 antagonist use. In the first week after implementation, this figure changed to 80% cimetidine, with little or no reaction by the medical staff. . . . Overall acceptance of the recommendation to switch to cimetidine was high, with no controversy evident . . . [T]here was an indirect effect as oral H_2 antagonist use shifted from predominantly ranitidine (75%) to predominantly cimetidine (73%). . . . In an informal survey of physicians, all indicated that they had no patient-management problems and that their patients had not experienced adverse effects resulting from the decision."—D.S. Rich, Director of Pharmacy Services, The University Hospital at Boston University Medical Center, published in American Journal of Hospital Pharmacy, September 1989.
- "Review of the literature comparing the two agents demonstrates equivalent efficacy of cimetidine and ranitidine in the therapy of duodenal and gastric ulcers . . . the potential cost savings to the institution from implementation of these formulary policies [to place only cimetidine on the formulary] is $100,000 to $130,000 over the next two years."—Albany Medical Center [New York] Pharmacy Newsletter, September 1989.
- "Aggressive promotional tactics by the manufacturers of [H_2 antagonists] lead to confusion about the comparative efficacy and safety of these drugs and contributes to inappropriate use. Recently, significant cost reductions (for cimetidine] led to a reevaluation of the comparative safety and efficacy of the parenteral (H_2 antagonists] cimeitidine, famotidine, and ranitidine. The hospital's Pharmacy & Therapeutics Committee decided that these three agents were therapeutically equivalent for adult patients not receiving theophylline, warfarin, or phenytoin . . . Cimetidine has been selected as the primary adult (H_2 antagonist] for this hospital, a decision which will reduce [H_2 antagonist) costs at Yale-New Haven Hospital by $100,000 annually. "—R.L. Fisher, M.D., Assoc. Prof., Gastroenterology, Yale School of Medicine, published in "Drugs In Patient Care',, Yale-New Haven Hospital Department of Pharmacy Service, August 1989.
- Misoprostol [Cytotec, a new expensive anti-ulcer medication not in the H_2 antagonist group] "does not appear to offer any advantages over the H_2 receptor antagonists currently in use."—VAMC Memphis, TN. Clinical Pharmacy Newsletter, May, 1989.
- "In (the UNC Pharmacy's] review of the literature, cimetidine, ranitidine, and famotidine are judged to be pharmacologically different yet therapeutically equivalent in the management and prevention of peptic ulcer disease."—Univ of North Carolina Memorial Hospital, April, 1989.
- ". . . the FDA recently sent letters to U.S. state formulary boards, which stated that 'there are no adequate and substantial data of which we are aware' that show Zantac [ranitidine] to be superior to Tagamet [cimetidine] in overall safety and effectiveness."—Univ of Missouri Hospital and Clinics Newsletter, December 15, 1988.
- "Therapeutic trials indicate that famotidine 20 mg b.i.d. or 40 mg at bedtime is as effective as standard doses of cimetidine and ranitidine for healing duodenal ulcers . . . [t]he overall incidence of adverse effects observed with famotidine appears to be similar to that reported for cimetidine and ranitidine."—RR Berardi, TM Tankanow and TT Nostrant. *Clinical Pharmacy,* 1988;7:271–84.
- "Overall, the scientific literature does not document any clinical advantage of famotidine over ranitidine."—M.E. Rose (VAMC Martinez, CA). "Famotidine", *VA Practitioner,* 1987: 51–61.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

(Note: This category of drugs represents 3%–10% of Medicaid drug spending.)

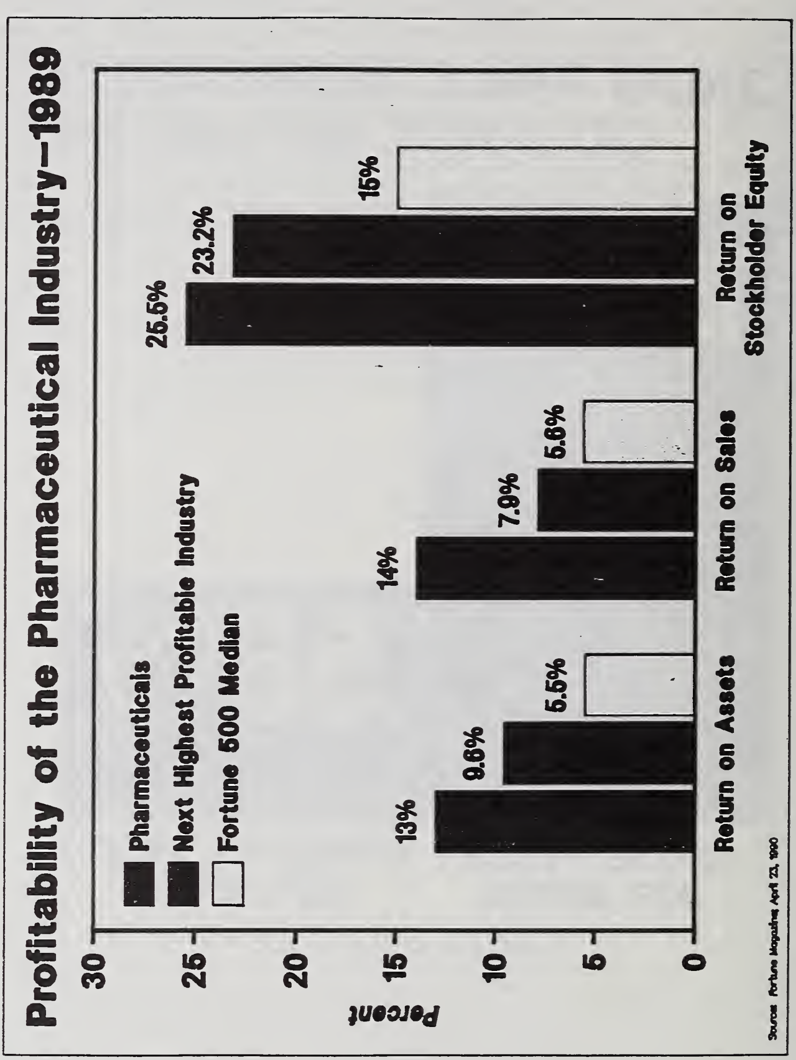
- "Based on the fact that there are currently many choices among NSAIDs on the GHC [Group Health Center] formulary, and diclofenac appears to offer no unique advantage, the Pharmacy Department recommends that diclofenac [Voltaren] not be added to the formulary. "—Drug monograph on diclofenac sodium by Group Health Cooperative of Puget Sound, March 1990.
- "There is still no evidence, however, that some NSAIDs are consistently more effective than others. . ."—KE Sack, MD. "Update on NSAIDs in the Elderly."—*Geriatrics,* 1989; 44(5):71-90.
- "The cost of diclofenac [Voltaren] is greater than NSAIDs that are generically available and approximately equivalent to the other available NSAIDs. . . . At this time, its main place in therapy appears to be as an alternative agent for patients not responding to or not tolerating other equally effective, but less expensive drugs."—Geisinger Medical Clinic Drug Review, December 20, 1988.
- "No clear advantage as regards therapeutic benefit or side effects profile for diclofenac [Voltaren] versus other formulary NSAIDs [aspirin, diflunisal, ibuprofen, indomethacin, naproxen piroxicam, tolmetin, and sulindac] has been shown."—Medical College of Virginia, October 19, 1988.
- "Claims that the NSAIDs differ significantly in their side effect profiles or efficacy have not been substantiated consistently in the literature."—University of Arizona Medical Center April, 1986.



DRUG PRICE INCREASES OUTPACE INFLATION

July, 1980–July, 1990

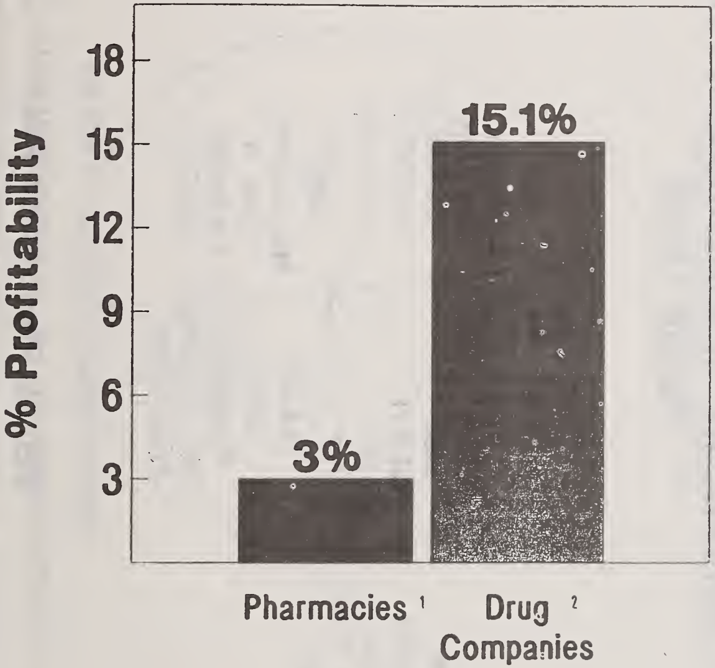
SOURCE: Bureau of Labor Statistics.



Profitability of the Pharmaceutical Industry—1989

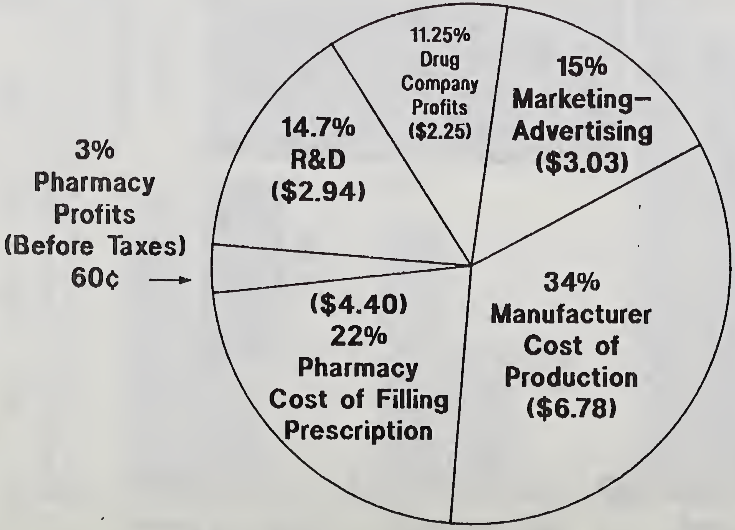
Source: Fortune Magazine April 23, 1990

**Drug Companies vs.
Pharmacies Profitability
1988**

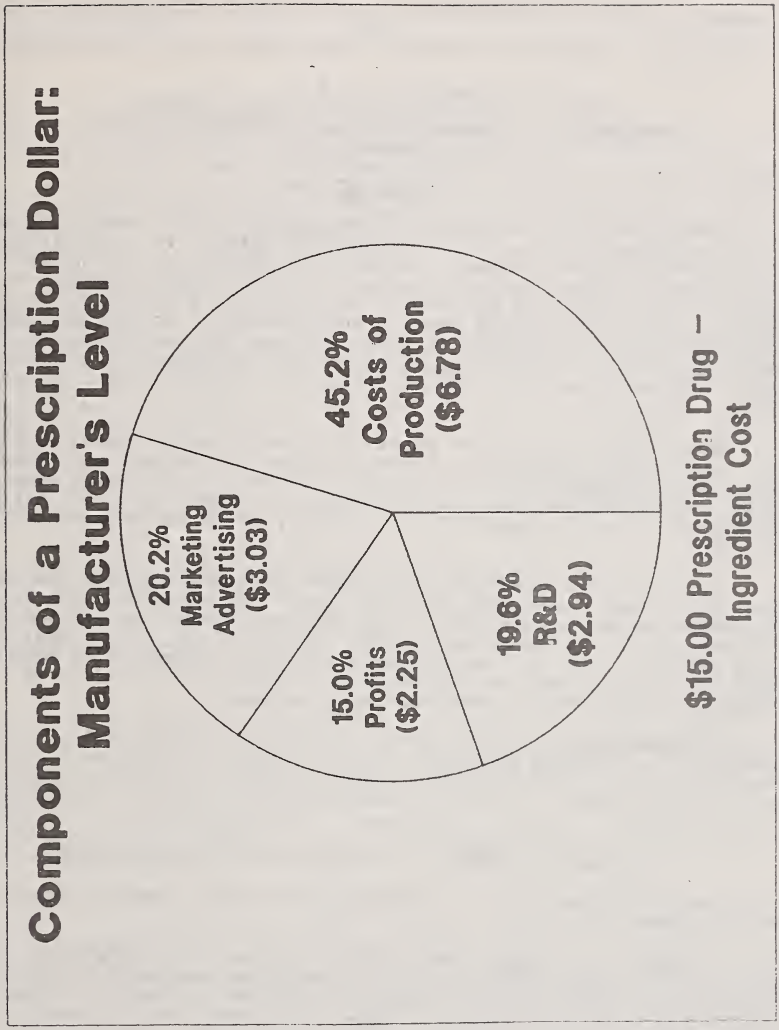


1 – Weekly Digest Survey; 1988 data before taxes.
2 – Standard and Poors Industrial Analysis – Health Care.

Components of Prescription Price: Retail Level



$20.00 Prescription Price



Components of a Prescription Dollar: Manufacturer's Level

ANALYSIS OF DRUG MANUFACTURER MEDICAID DRUG DISCOUNT PROPOSALS
and
NECESSARY ELEMENTS OF MEDICAID DRUG PRICE NEGOTIATION PLAN

prepared by the
Office of Senator David Pryor, (D-Ark)
Chairman, U.S. Senate Special Committee on Aging
September 1990

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o INTRODUCTION

Several drug manufacturers have proposed their own "national" plans for Medicaid drug cost containment: Merck, Pfizer, Glaxo and Upjohn. These manufacturers are to be commended for taking the initiative to offer their own solution to the urgent problem of containing rising drug prices for the Medicaid program. At first glance, these plans would seem to make available to the Medicaid program the same discounts on drug products that manufacturers generally offer to other large purchasers. For example, the DVA pays anywhere from 40 to 70% less than does Medicaid for the same drugs.

Unfortunately, as this paper will demonstrate, these proposals will not achieve substantive cost savings for the Medicaid drug programs. This conclusion is based on an analysis of each plan using the principles for Medicaid drug price reduction legislation developed by Senator David Pryor (D-Ark), which are summarized in the text.

In short, the analysis makes clear that any program that gives the drug manufactures free reign to reduce or eliminate the discounts or manipulate their "best prices" cannot be counted on to achieve significant savings for the multi-billion dollar Medicaid drug program. All the manufacturer proposals advanced to date have this shortcoming and are therefore not likely to be scored as "budget savers" for the Medicaid drug program.

~~In ana~~lyzing the~~se plans, th~~e necessary elements of a responsible Medicaid drug price reduction plan that uses a manufacturers' "best price" or "lowest price" approach to contain costs is outlined. A tabular summary of the analysis is attached.

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o SUMMARY AND ANALYSIS OF DRUG MANUFACTURERS' PLANS

The major provsions of each manufacturer's plan are described and analyzed below:

o MERCK AND PFIZER: These drug companies have proposed national plans which would require that drug manufacturers give Medicaid the "best prices" (through a rebate system) that they charge any other purchaser for their drug products. In return, each state would be required to put all that manufacturers' single source drugs on the state Medicaid drug program formulary.
Merck provides for a 10% minimum aggregate rebate, with a yearly phase-in (over a 5 year period of time) to the manufacturer's "best

price" for each single source product. Because Merck's "best prices" to purchasers are currently about 10% off the retail price, their plan would protect their discounts.

Pfizer has a three-year phase in to the "best price". However, in this plan there are no minimum discounts required for those manufacturers that offer small or no discounts on their drug products.

The very serious and obvious problem with both of these proposals is that the manufacturers have control over the "best price" on which the discounts would be based, and could easily eliminate the "best price" over time. The Medicaid programs would then have all these drugs on their formularies for which they were receiving little or no discounts, and the state Medicaid drug budgets would explode. In addition, we have evidence from states that have already signed an agreement with Merck that the company is not forcing all states to put all their single source drug products on the state Medicaid formulary as a condition of providing the "best prices". This fact is very important because all the manufacturers' proposals contain this requirement.

o GLAXO: In return for placing all its single source drugs on state Medicaid drug formularies, Glaxo is offering the Medicaid program the price that it offers to Independent Practice Association (IPA) model HMOs. Glaxo has a philosophical difference with Merck and Pfizer on this issue. The assumption within this proposal, therefore, is that Medicaid deserves some intermediate price, not a manufacturer's "best price."

In the scheme of things, these HMOs receive only very small discounts as compared to discounts offered by manufacturers to other purchasers. For example, the federal goverment usually receives the best discounts from drug manufacturers, followed by hospitals, staff and groups model HMOs, and then the IPA-type model HMOs, which are just below the manufacturer's regular retail prices. In addition, it is impossible for this to be a national plan because many manufacturers do not provide discounts to the IPA-model HMO class.

Glaxo's rationale for proposing this type of plan is very simple. The company gives deep discounts (about 67% off retail) to the DVA on its number one selling drug, Zantac. It apparently does not want to extend these same "best prices" to the Medicaid program on this or any other drugs that it deep discounts. In addition, under this plan, manufacturers would be able to raise or eliminate their "best prices" over time like the Merck and Pfizer plans.

o UPJOHN: By any measure, Upjohn's plan is a poorly thought out and totally unacceptable plan. It does not tie the amount of the rebate to the price of the drug at all or even offer Medicaid a "best price". It provides for a flat $1.36 rebate for each Medicaid prescription dispensed. Taking this thinking to its logical conclusion, if an Upjohn product cost Medicaid $40.00, the rebate would cost Upjohn $1.36 or 3.4% of the ingredient cost.

If a generic prescription drug cost Medicaid $3.00, the rebate would cost the generic manufacturer the same $1.36 or 45% of ingredient cost. In addition, if a stock bottle of 1000 generic tablets cost $3.00, and the pharmacists was able to fill 10 Medicaid prescriptions with the 1000 tablets (10 prescriptions, 100 tablets each), the generic manufacturer would be required to rebate $13.60 to Medicaid when the manufacturer sold the product for $3.00! In other words, the generic industry would be paying the Medicaid program $4 for every $1 of sales! This would be grossly unfair to generic manufacturers who will be forced to overwhelmingly and disproportionately bear the burden of cost containment under this appraoch.

However, it is easy to understand why Upjohn advocated this approach. Upjohn is also a deep discounter, and does not want to provide these similar discounts to Medicaid. On its popular drug Motrin, the difference between the Medicaid price and the DVA price is about 62%.

Perhaps more disturbing about Upjohn's proposal is not its unrealistic and inequitable approach, but the subliminal intimations in its proposal that drug manufacturer "best price proposals carry the additional liability of stimulating price inflation in those classes of trade which enjoy discounts such as the Veterans Administration (sic) and tax-supported institutions such as state mental institutions." (see p. 8 of the Upjohn proposal). It is unacceptable that Upjohn would hold the threat of removing its discounts to DVA and other purchasers over the heads of the Members of Congress to receive favorable reaction to its plan. Isn't the Medicaid program, the tax-supported program for the poor, entitled to the same discounts offered to other tax-supported programs?

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o CRITERIA FOR ANALYSIS

The principles that have been advocated by Senator Pryor to evaluate Medicaid drug price reduction plans are used below to further analyze each manufacturers' proposal. These principles are:

1) Medicaid deserves nothing less than a manufacturer's "best price; any "best price" approach should guarantee that these prices will not increase or be eliminated over time and negate the value of rebates;
2) The focus on cost containment should be on single-source and innovator multi-source drugs, those categories of drug expenditures most responsible for exploding Medicaid drug program costs;
3) The Secretary of HHS should have statutory authority to implement an alternative plan if cost-savings are not achieved;
4) There should be penalties for manufacturers that attempt to "game" the system;
5) There should be restitution to pharmacists for draconian reimbursement cuts of the past decade.

o MEDICAID DESERVES THE "BEST PRICE"

The only drug manufacturer plans that should be seriously considered by Congress are those that offer the Medicaid program the "best price" or "lowest price" that the manufacturer makes available to any other purchaser of its drug products. Because it is the tax-payer funded program for the poor, Medicaid deserves the same access to the "lowest" or "best prices" that manufacturers offer to these purchasers. In many cases, these "best prices" are already being offered to federal government agencies, such as the DVA or DPSC.

If anything less than the "best price" is being offered to Medicaid, manufacturers are still providing "second class treatment". Both the Merck and Pfizer plans recognize that Medicaid is entitled to this "best price". The Glaxo and Upjohn plans simply do not and are therefore "non-starters".

o GUARANTEES TO MAINTAIN A "BEST PRICE" ARE NEEDED

It is important to note that none of the manufacturers' plans developed to date have any provision to guarantee that the the manufacturers will not simply raise or eliminate their "lowest or best" price over time, negating the value of the rebates to Medicaid. If Congress decides that it wants to use a "best price" approach to contain Medicaid drug costs, then it must find a way to prevent manufacturers from increasing or eliminating their "best prices" over time.

Congress needs only to look at recent issue taken up in May by the Senate Subcommittee on Antitrust, Monopolies, and Business Rights to see why protecting the "best price" for Medicaid drug programs is important. The issue related to drug manufacturers' providing substantial rebates to the states for infant formula provided in the WIC program. After a few years of drug manufacturers' offering a program of substantial rebates to states for infant formulas-- up to 80 percent off the retail price -- drug companies tried to push prices higher in 1989 for these formulas and negate the value of the rebates.

These actions have threatened the fiscal solvency of the WIC programs and have jeopardized access to food supplied by the program to to millions of infants. If Congress places the determination of the "best price" in the hands of the drug manufacturers, state medicaid drug programs could face the same fiscal and access problems as the WIC programs are facing right now. This would create a worse situation than exists now in the states.

o FOCUS PRIMARY ATTENTION ON DRUGS CREATING GREATEST PROBLEMS

The focus of drug cost containment in the Medicaid program should be on "single source drugs" and "innovator multi-source drugs." To understand why, the categories of Medicaid drug costs should be defined:

(a) single source drug products are drugs on patent for which there is currently only one manufacturer or supplier, or for which there is a cross-licensing/marketing agreement between two manufacturers; (eg. Mevacor, used to lower cholesterol).

(b) innovator multiple source drug products (IMSDPs) are the original patented brand of a product that is now a multiple-source drug; (eg. Valium is the innovator multiple source drug of "diazepam", now currently available in generic versions from several manufacturers.)

(c) non-innovator multiple source drug products (NIMSDPs) are drug products made by manufacturers that do not hold the original patent for the product. These are the true "generic drugs." (eg. this category would include all makers of "diazepam" except Roche, since it holds the original patent or NDA on Valium.)

(d) nonprescription drug products are those drug products generally available without a prescription. (eg. aspirin, antacids).

Clearly, categories (a) and (b) should be the target of cost containment efforts since they are the highest-priced products in the market and have been the primary cause of unchecked drug price inflation over the past decade.

a) MINIMUM REBATE ON EACH "SINGLE SOURCE" DRUG PRODUCT

State medical assistance programs should be entitled to a minimum rebate on manufacturer single source and new drug products. This is because manufacturers' discounts or rebates on these products are relatively small for the first few years after introduction to the market, especially if there is no therapeutic competition to that product. Once the product faces therapeutic or generic competition, the manufacturers' rebates increase. Therefore, it is not likely that Medicaid programs will receive substantial savings from single source products in the early years after introduction. For this reason, if Medicaid programs are going to cover single-source and new drug products, Medicaid should receive a minimum rebate percent for single source and new drugs, regardless of the manufacturer's current discounting policies for these drugs.

b) "BEST PRICE" ON INNOVATOR MULTI-SOURCE DRUG PRODUCTS (IMSDPs)

All the manufacturers plans developed to date exclude from their rebate plan a major drug expenditure component for the Medicaid programs: innovator multiple source drug products (IMSDPs). It is essential to include these products in any rebate plan developed because almost all manufacturers of single-source drug products also have a substantial number of high-priced IMSDP's in their product mix for which Medicaid incurs significant expenditures.

This happens when the physician writes a "restrictive prescription" for a certain brand of a multiple source product. For example, if the physician writes a prescription for "Valium", and does not indicate "brand medically necessary", then the pharmacist should dispense a generic version of diazepam in stock. The "HCFA upper limit" for the NIMSDP drugs applies in this case. However, if the physician indicates "brand medically necessary", the HCFA reimbursement limits do not apply, and the Medicaid program has to pay for the prescription in the same manner in which it pays for single source drugs. (See State Medicaid Manual, Part 6- Payment for Services, Transmittal 12, April 1989). When the physician indicates that a particular brand of a multiple source product is needed by the patient, it essentially creates a "single source of supply."

Because Medicaid expenditures on IMSDPs represent a steady source of revenue growth for the drug manufacturers, all their plans proposed to date exclude these from any discount or rebate system that might be developed.

There are several additional reasons why it is very important to include IMSDP's in any final drug price negotiation plan:

o PATENT EXPIRATIONS: Many "popular" single source drugs are soon coming off patent. (For example, Pfizer's Procardia comes off patent in 1991, a drug with $228 million in sales. Dow's Seldane, a popular antihistamine, comes off patent in 1992. It had sales of $118 million.) Because they are currently single source products, states would now have to put these drugs on their formulary in exchange for the "best price" under the manufacturers' plans.

Once these drugs are multi-source, manufacturers are no longer required to give "best prices" under their plans. However, since so many patients will be using these drugs, states will receive a tremendous amount of pressure from beneficiaries and providers to continue to cover these drugs on their formularies. In addition, manufacturers may put pressure on the states to keep the drugs on the formulary by "suing" states. This is a tactic they have used successfully in the past. Therefore, rebates and "best prices" must apply for IMSDPs.

o IMSDPs PRICES CONTINUE TO CLIMB AFTER PATENT EXPIRATION: When a single source drug comes off patent and competition is introduced, the price of drug does not fall, it remains the same or goes higher to recover lost revenues from generic competition. Because of the significantly increased competition from generic versions, the drug manufacturers have to "step-up" their marketing expenditures for these drugs, driving the prices they charge for these products even higher.

o IMSDPs ARE HIGHLY DISCOUNTED TO OTHER PURCHASERS RIGHT NOW: To obtain a certain market share for itself in a competitive market with generics, the manufacturer of the IMSDP's will undercut the prices of NIMSDPs to obtain access to a hospital or managed care formulary, or the DVA system. Medicaid be entitled to these same "low prices" for IMSDPs when a restrictive prescription has been issued by the physician.

o THE R&D COSTS FOR A IMSDP HAS LONG BEEN RECOVERED: Six or seven years of marketing exclusivity for a single source drug product is a far sufficient time for the manufacturer to recover the cost of researching and developing the single source product and making up for "lost ventures" into research that did not produce either a "block-buster" or "me-too" drug product.

Because of the highly-competitive nature of the NIMSDP marketplace (generics), the Medicaid program is already receiving substantial savings on this category of expenditures. However, small additional savings may be realized for Medicaid from NIMSDP's. One strategy that has been suggesting to wring additional savings from the true cost-saving generics is to lower the HCFA upper limit from 150% of the lowest generic AWP to 120%. This would force pharmacists to dispense lower-quality generic products to Medicaid patients, since they would have to buy "cheaper" generics to come under the HCFA upper limit. The result would be a system of "second-class" medical care for Medicaid beneficiaries.

o STATUTORY AUTHORITY GRANTED TO THE SECRETARY

In any final plan developed, there should be realistic incentives for the entire drug industry to offer substantial and continuous discounts and rebates to Medicaid. Therefore, if at any time, the aggregate level of the rebates received by the states from the drug manufacturers falls below a certain percentage or level in any one state in any year, the Secretary of HHS should have the statutory authority to implement a system of negotiation with the industry to control Medicaid drug costs.

The drug industry fears negotiating with the federal government because of its tremendous pharmaceutical purchasing power. The Secretary should have the statutory authority to fall back on a plan of negotiating with the drug manufacturers by selective contracting or competitive bidding within therapeutic classes if the savings from rebates start to shrink.

The drug industry's continued cooperation with the Medicaid program is most assured and the solvency of the state medical assistance plans is best protected if there are unquestionable and significant incentives for the continuation of significant manufacturer discounts on single source drugs and IMSDPs. This is best achieved if the Secretary has the statutory authority to implement an alternative program of negotiating. None of the manufacturer plans to date includes such necessary provisions.

o SUFFICIENT GUARANTEES AGAINST MANUFACTURERS' GAMING THE SYSTEM

All of the manufacturers' plans require that states place all of that manufacturers' single source drug products on the state's formulary as a condition of receiving a "best" or "lowest" price. (NB. Just to reiterate. In some cases, Merck has still given their "best prices" to states which refused to put all their single source drugs on the state Medicaid formulary.)

State medical assistance plans will feel more secure about entering into this type of agreement with the drug manufacturers if there are sufficient and harsh penalties for those drug manufacturers that might attempt to "game" the new system. For example, a small manufacturer with one or two drug products might give states their "best prices" for a year or two in order to get their products on state formularies, knowing that they would not renew the agreement after expiration.

Under this scenario, the state may be forced to continue to cover the total cost of the product(s) for all those patients that are taking the product(s). Although, under the manufacturer plans, the states would not have to cover these after the agreement is terminated because the manufacturer was not offering the state the "lowest price", the pressure on the states from beneficiaries and providers to continue to cover the product(s) on the state Medicaid drug formulary will certainly be intense.

Credibility is lended to this concern because the manufacturers' plans developed to date only require the manufacturer to have a one year contract with the state medical assistance program for rebates. Why are drug manufacturers unwilling to enter into long-term contracts with Medicaid when they routinely do so with other purchasers of their products?

- RESTITUTION SHOULD BE MADE FOR PHARMACISTS' REIMBURSEMENT CUTS

Retail pharmacy has borne the brunt of Medicaid drug cost containment initiatives over the past number of years. The current system of reimbursement produces an average loss of 8 percent on retail pharmacy's Medicaid business, according to CBO and other estimates. To insure that pharmaceutical services continue to be widely available and accessible to Medicaid beneficiaries, and to encourage pharmacists to counsel Medicaid patients on the proper use of their medications, pharmacists should receive restitution for the draconian cuts inflicted on their reimbursement over the last 10 years in any final plan enacted. None of the drug manufacturer plans has any provisions for increasing pharmacy reimbursement.

On a final note, all the manufacturers' plan recognize that there is a simple, widely-used, time-tested system in place to provide the state medical assistance programs with the best price: a manufacturers' rebate system. Therefore, the argument that discounts on drug products can only be provided to those purchasers that actually take possession of drug products is debunked.

Further information about the manufacturers plans or further analysis can be provided by the staff of the Special Committee on Aging (X- 45364).

U.S. SENATE SPECIAL COMMITTEE ON AGING

ANALYSIS OF DRUG MANUFACTURER MEDICAID DRUG DISCOUNT PROPOSALS

September 1990

Characteristic	MERCK	PFIZER	GLAXO	UPJOHN
1. Recognizes that Medicaid deserves "best price".	YES	YES	NO	NO
2. Provides sufficient and unquestionable guarantees that a "best price" is maintained.	NO	NO	NO	NO
3. Minimum rebate on each "single source" product guaranteed?	NO	NO	NO	$1.36
4. Minimum rebate on each "innovator multi-source" product guaranteed?	NO	NO	NO	$1.36
5. Statutory Authority Granted to Secretary to Implement Alternate Cost Savings Plan?	NO	NO	NO	NO
6. Sufficient Guarantees Against Manufacturers' Gaming System?	NO	NO	NO	NO
7. Recognizes that Pharmacists should receive restitution for reimbursement cuts.	NO	NO	NO	NO

SINGLE SOURCE DRUG PRODUCTS

Price Comparisons -- July 1990

DRUG	APPROVAL DATE	MEDICAID PAYS(a)	FEDERAL GOVT PAYS (b)	PERCENT DIFFERENCE(c)
Feldene 20mg (piroxicam) Pfizer, Inc.	4/82	1.68	.87	93%
Zantac 150mg. (ranitidine) Glaxo, Inc.	6/83	1.18	.79	49%
Seldane 60mg. (terfenidine) Marion-Merrell Dow	5/85	.61	.40	53%
Mevacor 20mg. (lovastatin) Merck	8/87	1.55	1.25	24%
Prozac 20mg. (fluoxetine) Lilly	12/87	1.40	1.20	16%

(a) Medicaid reimbursement for single source drugs based on pharmacists Estimated Acquisition Cost (EAC). For most states, this is AWP-10%. AWP is the Average Wholesale Price as reported in the Redbook or Bluebook.

(b) Represents the "best prices" paid by a federal government purchaser. Under a "best price" rebate plan, Medicaid might pay even lower prices if another purchaser was getting a "better deal" than the federal government.

(c) In general, newer drug products are not as heavily discounted as older products.

INNOVATOR MULTI SOURCE DRUG PRODUCTS

Price Comparisons -- July 1990

DRUG	MEDICAID PAYS (a)	FEDERAL GOVT PAYS (b)	PERCENT DIFFERENCE
Calan 80mg (verapamil) Searle	.32	.026	1130%
Desyrel 100mg (trazadone) Bristol Myers Squibb	1.19	.63	88%
Ativan 1mg. (lorazepam) Wyeth-Ayerst	.51	.01	5000%
Motrin 400mg. (ibuprofen) Upjohn	.16	.06	166%
Inderal 40mg. (propranolol) Wyeth-Ayerst	.40	.06	566%

(a) Medicaid reimbursement for innovator multiple source drugs based on the pharmacist's Estimated Acquisition Cost (EAC). For most states, this is AWP-10%. AWP is the Average Wholesale Price as reported in the Redbook or Bluebook.

(b) Represents the "best prices" paid by a federal government purchaser. Under a "best price" rebate plan, Medicaid might pay even lower prices if another purchaser was getting a "better deal" than the federal government.

RESPONSES TO COMMON QUESTIONS AND CONCERNS RAISED IN SEPTEMBER 17, 1990 SENATE FINANCE COMMITTEE HEARING ABOUT S. 2605 AND S. 3029

prepared by the staff of the
U.S. Senate Special Committee on Aging
September 1990

At the Senate Finance Committee Subcommittee on Health for Families and the Uninsured hearing on Monday, September 17, 1990, several questions and concerns were raised by interested parties concerning provisions in both S. 2605, the Pharmaceutical Access and Prudent Purchasing Act and S. 3029, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act. The purpose of this memo is to respond briefly to these issues.

ISSUE 1 - PRIOR APPROVAL PROGRAMS

As of September 1990, 25 state Medicaid programs required some form of prior authorization for an extremely small number of prescription drug products or over-the-counter (non-prescription) drug products. In general, prior approval programs are used by many states -- for a very small percentage of Medicaid-covered prescription drugs -- to assure that the prescriptions dispensed are medically necessary.

Under S. 3029, states would be required to implement prior approval programs for those drugs for which the state is NOT receiving a rebate from the manufacturer. The bill does not require or even encourage states to implement prior approval for drugs for which the states receives rebates from manufacturers. The states have asked for the flexibility, however, to retain their current ability to use prior approval for a small number of drugs even if they are given rebates.

In some prior approval programs, however, the "turn-around" on obtaining approval for the physician to prescribe or the pharmacist to dispense the drug can take several hours to several days. In some states, physicians have to wait for an approval to be mailed to them, a process that can take weeks. This is not in the interest of good patient care.

To make these PA programs more responsive to health care providers, Senator Pryor's legislation provides that state Medicaid plans can only operate prior approval programs for drug products if they meet certain criteria. That is, the PA programs should be available 24 hours/day, 7 days a week, and provide an immediate response to the physician's or pharmacist's request.

In the final analysis, the approach taken in S. 3029 is a careful balancing of the interests of physicians and State Medicaid programs. States, including Michigan and California, have insisted that they be allowed to operate prior approval programs. Although the manufacturers' national proposals say that any type of "prior approval" restrictions on drugs subject to a rebate are "unacceptable" to them, drug manufacturers that have already negotiated rebate agreements with certain states have allowed states to place some products on prior approval programs. On Monday, the state of California testified that it would not accept the manufacturer's requirements that the state place all the manufacturer's products on the state formulary as a condition for the rebate agreements.

In the written testimony submitted to the Subcommittee, the National Governors' Association said:

> "States are concerned with the language in the manufacturers' proposals to eliminate the prior authorization mechanisms. Prior approval serves two important functions in the Medicaid program. It allows authorization for a drug not covered under the state formulary and enables states to provide, on a limited basis, high-cost prescription drugs it would otherwise not be able to afford. Prior authorization is an important mechanism to insure appropriate and medically necessary utilization of drugs. States must maintain the flexibility to determine what drugs are covered by the Medicaid program to insure program stability and to ensure that quality and appropriate care is provided.

In written testimony to the Subcommittee, the American Public Welfare Association, representing the State Medicaid Directors, said they are:

> "... concerned about the open formulary requirements coupled with the exception process (prior approval) outlined in the bill. There is also concern about the costs and feasibility of the prior approval process outlined in the bill, and some concern about the impact of requiring immediate approval ..."

Most outpatient third party prescription drug plans require some sort of prior approval for very expensive or unique drugs. Medicare and 67% of private health plans require a physician to call in for prior approval before a hospitalization will be paid for. The efficiency of prior approval programs will be enhanced by use of electronic claims processing, for which multi-State demonstrations would be established under both S. 2605 and S. 3029. Through this type of system, pharamcists will be able to know instantaneously if the physician has received prior approval to dispense the drug. It is conceivable that such systems could even be connected to physicians' offices.

The staff of the Aging Committee will continue to work with the states, the AMA and other interested parties to ensure that, to the extent possible, prior approval programs help the states control utilization on select drugs where the state wants to do this, but that they do not interfere with good medical practice or compromise the quality of patient care.

ISSUE 2 -"BEST PRICE" and INDEXING PROVISION: ARE THEY PRICE CONTROLS?

Two issues need to be addressed in this section: first, the "price" in the market to which the value of the Medicaid rebate should be pegged; second, the issue of "indexing" as a mechanism to contain the rate of growth of Medicaid drug program expenditures.

a) Selection of the "Best Price"

Several drug manufacturers, representing a substantial dollar volume of the Medicaid market, now or have tentatively endorsed the concept of giving Medicaid discounts by offering that manufacturer's "best price" in the market. These plans are being offered both by companies that give small discounts and those that give large discounts.

By any criteria, Medicaid deserves a manufacturer's best price in the market, and in many cases, this would be the price that federal government purchasers have been able to negotiate with federal government purchasers, like the Department of Veterans' Affairs (DVA). Several manufacturers have contended that locking them into a their "best price" offered on September 1, 1990 (indexed by the CPI) would be unfair since different manufacturers offer different levels of rebates. In addition, the manufacturers contend that the federal government represents a very small percent of their business (1-2%), and it would be therefore unfair to base a price to Medicaid on the prices given to this small percent of the business. To be fair to those manufacturers that do offer large discounts in the market, a manufacturer's rebate would be limited to 25% of their total product sales in the state under S. 3029. This "floor" effectively obviates the argument that the plan is inherently unfair to manufacturers that offer large discounts. One company, which is a deep-discounter, is offering us their "best price" without the floor!!

In many cases, however, this "1-2%" of the business may be the single largest contract that a manufacturer has with a single client. Manufacturers say that the "best price" should be the price they offer larger customers, such as HMOs, since this class of purchaser represents 20 to 30% of their business. This class of trade, however, may in reality represent the sum total of many, many smaller single contracts that manufacturers have with HMOs. For example, a company may have individual contracts with hundreds of HMOs, each of which represents only 0.05 to 0.06% or less of the company's business. When all these very small contracts are added cumulatively, it may represent 20 to 30% of the company's business.

Economic principles say that the larger the volume you buy, the better the price you obtain. Thus, while the HMO business may represent a large cumulative market for a company, individually these HMOs do not have the purchasing power of the single DVA, which buys almost $900 million in drugs every year, and is able to negotiate very good prices. Since these prices to the DVA are competitively determined, and represent the "best prices" offered to a large or the largest single client that the manufacturer has, Medicaid should be entitled to these prices.

b) Indexing: Containing the Growth of Expenditures, Not Price Controls

Given that CBO, HCFA, OMB and other experts have indicated that the manufacturers are likely to raise their "best prices" over time, effectively erasing any savings for Medicaid, an indexing feature was used in S. 3029. This feature would insure that Medicaid payment for a certain drug would be no more than the manufacturer's "best price" for the drug in the market as of September 1, 1990, indexed to the CPI. This is a similar concept to indexing features that have been acknowleged to be needed by Congress in the DRG and the RBRVS programs to control the growth rate of expenditures

Some have alleged that this "indexing" is tantamount to price controls. There is a difference, however, between indexing and price controls. Price controls are usually defined as arbitrary price setting. Under S. 3029, the index is not tied to a price that Senator Pryor or anyone else for that matter would like; it is tied to a price that has been competitively determined in the marketplace through negotiations between the drug manufacturers and purchasers.

Although obviously concerned about all purchasers of prescription drugs, Senator Pryor's bill allows the manufacturers to retain the freedom to set any price at any time in any market to any purchaser, including the Department of Veterans Affairs. It would be more appropriate to label the index in S. 3029 as a "cap" on what Medicaid will pay a manufacturer for a certain drug product, with appropriate allowances for inflation.

This "cap" is based on a competitively-determined marketplace price. Therefore, should marketplace forces allow the price in the market to go lower that the indexed price, Medicaid would not pay the "indexed" price, but the lower price which has also been "competitively-determined".

For many years, "caps" have been in place in the Medicaid reimbursement system. Pharmacists' reimbursement for single source drugs and innovator multiple source drugs is "capped" at their "estimated acquisition cost" (EAC). Reimbursement for generic drug is "capped" at the federal upper limit for generic drugs. The bill will now focus the caps on the ingredient cost, since focusing these caps on the reimbursement level has not affected the growth rate of the ingredient cost of the product.

Finally, beyond the fact that HCFA, CBO, and OMB have concluded that some sort of indexing is needed to control the growth rate of expenditures in drugs, it has been made clear to most Finance Committee members that some sort of index would be acceptable to some in the drug industry.

ISSUE 3 - THERAPEUTIC SUBSTITUTION

The question of whether S. 2605 contained "therapeutic substitution" was resolved at the hearing. Therapeutic substitution occurs when the pharmacist dispenses another drug product without the physician's knowledge. The mechanism incorporated in S. 2605, therapeutic interchange, occurs only when the physician has given permission to dispense a different, but similarly-acting drug product to the patient. Clearly, S. 2605 does not contain this provision.

ISSUE 4 - NEED FOR FEDERAL LEGISLATION

The need for federal legislation in this area is apparent for several reasons. First, there is no guarantee that, without federal legislation, all manufacturers will sign rebate agreements with all states, or that rebates will continue after a few years. There is particular concern for small states, where there is very little or no incentive for manufacturers to negotiate with the state Medicaid programs. By using a national approach, we insure that all manufacturers do their part and that all Medicaid patients in all states -- small and large -- have access to needed medications. Finally, the drug manufacturers have conceded that federal law is needed by offering their own national proposals.

September 12, 1990

Senator Howell Heflin
728 Hart Senate Office Building
Washington, DC 20510

Dear Senator Heflin:

Recently, you received a letter from the Alabama Pharmaceutical Association requesting your support of Senator David Pryor's Pharmaceutical Access and Prudent Purchasing Act (S.2605). The pharmacists of Alabama and your constituents have carried the burden of increasing pharmaceutical prices for too long. The discriminatory pricing practices of the pharmaceutical manufacturers have place an undue burden on the citizens of Alabama. S.2605 begins to address this issue and provides the Medicaid program with the ability to control escalating costs and provide quality health care to the citizens of Alabama.

The opposition have made several misleading statements and have tried to place an added burden on pharmacists and tax-payers. For the past several years, pharmacists have taken cuts in their reimbursements and have absorbed many price increases initiated by the pharmaceutical manufacturers. Our patients have given through co-payments. But the manufacturers continue to receive their price increases from the retail public, including Medicaid. What we're asking for is "Equal Access" to the special pricing currently offered to hospitals, HMO's and certain government agencies. Why shouldn't Medicaid receive these same prices?

In an attempt to get this bill through Congress, Senator Pryor has offered an alternate version to his original bill (S.2605). **The Alabama Pharmaceutical Association supports the concepts contained in this alternative, as well as S.2605.** The alternative version provides the following:

- Prescription manufacturers must provide the Medicaid program the same substantial discounts it now gives to other purchasers of its medications.

- Significantly expands Medicaid beneficiaries access to a wide range of FDA-approved prescription drug products and biologicals. Final control over the drug product selected for the patient is retained with the patient's physician. There are no provisions in this bill for therapeutic substitution or therapeutic interchange of drug products by pharmacists.
- Prior Approval Programs will be more responsive to physician needs. Minimum standards include; 24 hour, 7 day a week availability to physicians and immediate response.
- Establishing a comprehensive system of drug use review (DUR) that encourages pharmacists to counsel patients and avoid medication problems.
- Give incentives for states to develop and implement a cost-saving on-line pharmacy based electronic system to process Medicaid prescription drug claims.
- Restore Pharmacy Reimbursement Cuts by setting aside 10% of rebates received each year by the state.
- Reformation of Medicaid's Pharmacy Reimbursement System. It requires the state to perform an annual cost of dispensing study for the purpose of updating pharmacy dispensing fees, places a 2 year moratorium on any further reduction in drug product cost reimbursement for brand name drug products, and changes the federal upper limit on non-innovator multiple source drug products.
- Establishes a Drug Policy Review Commission, and
- Provides for demonstration projects and several studies to be conducted on DUR and pharmaceutical pricing practices.

Senator Heflin, I hope you will agree, that S.2605 is important to the pharmacists and citizens of Alabama. The Pharmacists of Alabama encourage your support of S.2605. If you have any questions, feel free to contact me. Thank you for your support.

Sincerely yours,

Mitchel C. Rothholz
Executive Director

AARP

September 14, 1990

The Honorable David H. Pryor, Chairman
Special Committee on Aging
G-31 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Pryor:

On behalf of the American Association of Retired Persons, I want to commend you for introducing the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act. Your legislation would have the important effect of lowering the cost of prescription drugs to the Medicaid program and improving Medicaid patients' access to needed medications.

The cost of prescription drugs increasingly presents a barrier to needed health care for many Americans. Indeed, for some, medicines have become unaffordable. Low-income persons and older Americans--those most likely to be Medicaid beneficiaries--are particularly vulnerable to rising prescription drug costs, both because they tend to be sicker and because they often live on fixed incomes.

For nearly a decade (1980-1989) prescription drug prices rose 128 percent, with an average annual increase of 9.5 percent. During the same period, the Consumer Price Index (CPI) for all items rose just over 50 percent, or 5.6 percent annually, on average. This increase in prescription drug prices (128 percent) is even more striking in that it has also exceeded the 99 percent increase in the medical care component of the CPI over the same period. A recent survey by AARP found that the cost of prescription drugs was the second most important reason why older Americans do not get their prescriptions filled.

AARP welcomes the opportunity to work with you and other members of the Senate to ensure that low-income Americans have access to the prescription medications they need. If we can assist you in any way on this legislation, please do not hesitate to call upon Tricia Smith of our Federal Affairs Department at 728-4841.

Sincerely,

Horace B. Deets

Horace B. Deets

APhA

American Pharmaceutical Association

2215 Constitution Avenue, NW
Washington, DC 20037
(202) 628-4410 FAX (202) 783-2351

The National Professional Society of Pharmacists

September 11, 1990

The Honorable David Pryor
Chairman, Senate Special Committee on Aging
Room G-41, Dirksen Senate Building
Washington, D.C. 20510

Dear Mr. Chairman:

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, has reviewed your proposal entitled "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act" and is pleased to convey our support for this important legislation.

We understand that this proposal is intended as an alternative to your earlier bill, the Pharmaceutical Access and Prudent Purchasing Act (S.2605) and responds to efforts to incorporate Medicaid drug pricing reforms into the budget reconciliation process. We believe both proposals to be viable alternatives that would advance patient care, facilitate access to prescription drugs and generate programmatic cost savings for the Medicaid program. Indeed your proposals are the only ones of which we are aware that will improve patient care and assure significant Medicaid savings.

We are pleased that your latest proposal carries over many of the concepts included in S.2605, specifically that drug manufacturers provide "best prices" to the Medicaid program and the recognition of the pharmacist as a critical professional in health care delivery. APhA believes that the S.2605 provision calling for marketplace pricing for pharmacist reimbursement is an appropriate mechanism given the intense competition that exists in pharmacy. However, we believe the approach taken in your most recent proposal implementing steps to restore fair reimbursement for pharmacists through a percentage set aside from manufacturer's rebates and annual dispensing fee updates based on economic studies by each state is a reasonable alternative.

You are to be commended for you continuing efforts to reform the pharmaceutical component of the Medicaid program. We believe the criticism you have encountered has been unfair, unjustified and based upon grossly inaccurate information. Your tireless efforts and those of your staff to assist Medicaid recipients, state government and the profession of pharmacy is greatly appreciated.

Sincerely,

John A. Gans, Pharm.D.
Executive Vice President

Families
USA
Families United for Senior Action

September 11, 1990

The Honorable David Pryor
United States Senate
Washington, DC 20510

Dear Senator Pryor:

Families USA appreciates your efforts to control costs and improve Medicaid beneficiaries' access to needed prescription drugs. The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990 is a well-balanced approach to controlling excessive inflation in Medicaid drug prices as well as increasing access to needed health care for the very poor. This effort will benefit low income elderly people, who represent a high percentage of Medicaid prescription drug beneficiaries and who are particularly vulnerable to cuts in the Medicaid prescription drug program and to the high rate of increase in prescription prices.

At a time of scarce resources, it is most important that we ensure that the Medicaid program is getting its money's worth. States and the federal government should not be paying unreasonably high prices for drugs. According to the most recent HCFA data, Medicaid prescription drug payments from 1973-1985 rose at an annual rate of 11.8 percent, while prescription drug use only rose at an annual rate of 2.2 percent.

High drug prices create access problems. Some states have instituted restrictive formularies. If a particular drug or entire classes of drugs are not on a state formulary, it is completely unavailable to Medicaid beneficiaries. In addition, some states restrict coverage to an arbitrarily determined number of prescriptions per month. As a result, many low income individuals are being forced to make choices between their health care needs and other basic needs.

Your bill will make it possible for those most in need of medical assistance, Medicaid beneficiaries, to receive the most appropriate drug at the best price possible. Families USA looks forward to working with you to enact the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990.

Sincerely,

Ronald Pollack
Ronald F. Pollack
Executive Director

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Formerly The Villers Advocacy Associates

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September 13, 1990

The Honorable Wyche Fowler
United States Senate
Washington, D.C. 20510

VIA FACSIMILE

Dear Senator Fowler:

On July 17, 1990, I wrote to you to ask for your support of Senator David Pryor's S.2605, the "Pharmaceutical Access and Prudent Purchasing Act of 1990" (PAPPA). I am in receipt of your response dated August 8, 1990.

As you are probably now aware, Senator Pryor has revised the original S.2605 and an alternative compromise bill has been introduced entitled the "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act" (S.3029). This letter is to advise you of our strong support for S.3029.

The alternative bill (S.3029) contains the same cost-saving provisions of the original legislation, estimated at $350 million for the first year. However, some of the provisions which affect medical policy decisions such as therapeutic interchange, have been removed. Additionally, if a physician determines that a specific patient needs a specific prescription drug which is not covered under the Pryor Medicaid Rebate Program, the physician may still prescribe the drug if medically necessary.

The pharmacists of Georgia support the legislation because the bill improves the delivery of quality patient care for Medicaid beneficiaries, enables equal access to equitable prescription drug prices for all American consumers, and establishes a mechanism (a percentage set aside from manufacturer rebates) to restore adequate reimbursement for pharmacists who participate in the Medicaid prescription drug program.

We appreciate the opportunity to provide you with our position on this important landmark legislation. We certainly hope you will consider co-sponsorship of S.3029. If we may be of any assistance to you or your staff on this or any other matter, please do not hesitate to call on us. Thank you for your continued support of pharmacy and pharmacists.

Sincerely,

GEORGIA PHARMACEUTICAL ASSOCIATION

Wayne

Wayne W. Oliver
Director of Governmental Affairs

cc: Senator David Pryor

IPhA **Illinois Pharmacists Association**
223 W. Jackson Blvd. • Suite 1000 • Chicago, IL 60606 • Phone 312/939-7300 • Fax 312/939-7220

14 Sep 1990

Honorable Alan J. Dixon
U.S. Senator
The Hart Building, Room 3126
Washington, D.C. 20510

RE: Medicaid Anti-Discrimination Drug Price and Patient Benefit Restoration Act of 1990

Dear Senator Dixon:

On behalf of the 2,600 members of the Illinois Pharmacists Association, I am pleased to present these comments in support of the Medicaid Anti-Discrimination Drug Price and Patient Benefit Restoration Act of 1990 (proposed alternative to S.2605). This Act would provide the Illinois Department of Public Aid an opportunity to significantly improve the quality and cost effectiveness of medical and pharmaceutical care to this state's most needy disabled citizens.

Taking advantage of purchasing power exercised in a multitude of other government-vendor relationships, this Act would require all those involved in Medicaid programs to work together in assuring cost effectiveness and quality (manufacturers, providers, patients, and states); provide states the financial wherewithal to upgrade physical operations to make use of more efficient processing and resultant data; and allow broad access to pharmaceutical products, while controling costs that might result from wider access through use of prospective and retrospective utilization review.

It is our view that Illinois would serve as an ideal state for a demonstration project on the effectiveness of on-line prospective drug utilization review and a demonstration project on the cost-effectiveness of pharmacists providing medication counseling services to patients.

The Illinois Pharmacists Association would welcome the opportunity to discuss these comments further or provide any other details with regard to this Act. We ask for your support of this proposed alternative Act to S.2605. We will be following the progress of this legislation and hope to see your vote in support of the Act.

Sincerely,
Mark A. Pilkington

Mark A. Pilkington, M.S., R.Ph.
Execuitve Director

cc: Senator David Pryor, Arkansas
Director Kathleen Kustra, IDPA

MISSOURI PHARMACEUTICAL ASSOCIATION
Your professional pharmacy association
in the state capital.

September 12, 1990

Senator John C. Danforth
249 A Russell Building
Washington, D.C. 20510

Dear Senator Danforth:

The members of the Missouri Pharmaceutical Association and the Foundation for Pharmaceutical Care wish to relay to you there support for the alternative legislation to SB 2605 that is being presented by Senator David Pryor. We feel very strongly that these changes will be very positive in the effort to hold down the escalating cost of providing medicaid pharmacy services.

We will be happy to answer any questions or supply any information that you or your staff may have or need.

We hope that you will support this important legislation.

Thank you for your consideration.

Sincerely.

George L. Oestreich, Pharm., MPA
Chief Executive Officer

410 Madison Street
Jefferson City, Missouri 65101
314-636-7522

N·A·R·D

NARD OFFICERS

NARD EXECUTIVE COMMITTEE

September 12, 1990

The Honorable David Pryor
Chairman
Senate Special Committee on Aging
SD-G31 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Pryor:

We are pleased to join the strong, broad based, bipartisan coalition supporting the "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990".

The Medicaid Anti-Discriminatory Drug Price legislation will provide the $3.5 billion Medicaid outpatient drug program equal access to manufacturer prices already available to other Medicaid components and nonprofit entities generally; including hospitals, HMO's, and mail order firms. By enabling the state Medicaid programs to access the current nonprofit manufacturer prices the program burden of cost containment will be shifted from the beneficiaries and pharmacists and will improve beneficiaries access to pharmaceuticals and pharmacy services which may have been reduced or eliminated by misguided cost containment approaches.

We support efforts to ensure equal access to equitable prescription drug prices for all American consumers.

The Medicaid Anti-Discriminatory Drug Price legislation addresses long standing priority concerns of the National Association of Retail Druggists. Like S.2605, it is landmark legislation. It will help assure equal access for the poorest among us while also relieving the extraordinary fiscal pressures on the Medicaid outpatient drug program.

The enactment of Medicaid Anti-Discriminatory Drug Price legislation is our top legislative priority for the remainder of the 101st Congress. We strongly support its inclusion in the Budget Summit agreement.

We look forward to working closely with you and the many health care and consumer groups supporting your legislation.

Our members serve 18 million persons daily and provide nearly 85 percent of the Medicaid pharmaceutical services and products. On behalf of these 40,000 independent retail pharmacies and the 75,000 pharmacists practicing in these independent settings, we pledge to leave no stone unturned in assisting you, Majority Leader Mitchell, and others in the enactment of this long pverdue legislation.

With warm regards,

Charles M. West

Charles M. West, P.D.
Executive Vice President

John M Rector

John M. Rector, Esq.
Vice President of
Government Affairs
and General Counsel

JMR/tww

National
Consumers
League
Founded 1899

815 15th Street NW • Suite 516 • Washington, DC 20005 • (202) 639-8140

Linda F. Golodner, Executive Director

September 11, 1990

Senator David Pryor
SR-267 Russell Senate Office Bldg.
Washington, DC 20510-0402

Dear Senator Pryor:

The National Consumers League supports the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990. Drug costs are now the third largest budget item for state Medicaid programs, growing faster than any other major part of the program. Individual states have tried, without success, to bring the medication costs down for Medicaid beneficiaries by negotiating with drug manufacturers for better prices. This legislation provides a framework to help states receive discounts available to other major drug purchasers. In order to receive the Federal matching dollars for Medicaid sales in all states, drug manufacturers would be required to provide each state's Medicaid program with the same discount offered to hospitals, HMO's and the Department of Veterans Affairs.

For a consumer receiving Medicaid benefits, an important part of this proposed legislation is the assurance that doctors can write prescriptions for any FDA-approved medications needed for an illness. Sometimes patients want and need a specific medication. With this legislation, Medicaid beneficiaries will have improved access to all medications.

The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act is a major effort to help control rising drug costs. The League applauds your initiative and interest in helping to solve this health care financing crisis.

Sincerely,

LINDA F. GOLODNER
Executive Director

Officers: Robert R. Nathan, Honorary Chairman • Esther Peterson, Honorary President • Jack Blum, President •
Ruth Jordan, Vice President • Bert Seidman, Vice President • Jane King, Secretary • Barbara Warden, Treasurer

New Jersey Pharmaceutical Association
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President Emeritus *HARRY MARGULIES*
Counsel *FREDERIC K. BECKER*

September 13, 1990

The Honorable Bill Bradley
Senate Office Building
Washington, DC 20510

Dear Senator Bradley:

The New Jersey Pharmaceutical Association, representing 3,500 practicing pharmacists in the state, many of whom own small independent community pharmacies, would like to file these comments with you regarding Senator David Pryor's efforts to control costs in the Medicaid Prescription Drug Program.

During the last decade, major prescription drug manufacturers raised their drug prices each year by a factor of 2 to 3 times that of the Consumer Price Index. As a result of these rapidly escalating drug costs in the program, both HCFA and the various state's Medicaid program administrators have targeted two groups for cost containment, pharmacist providers and Medicaid patients. HCFA's efforts to confiscate pharmacies earned discounts are well known nationwide. Various states have targeted the Medicaid patients by not allowing certain, expensive drugs onto the Medicaid Drug Formulary, thus denying patients the ability to obtain those drugs even if their physician believes that drug is the best drug for that patient's condition. In addition, the states have been facing budgetary problems themselves and thus have been unresponsive to pharmacist provider needs for an increase in their administrative allowance (professional fees), even though pharmacy providers are facing the same problems created by the continued march of inflation.

We urgently request you to support Senator David Pryor's efforts to obtain fair compensation for pharmacy providers in the Medicaid program by requiring states to do an annual survey and adjust pharmacist payments appropriately.

Our pharmacist members thank you for considering these comments and would very much appreciate your support.

Respectfully,

Leon R. Langley

Leon R. Langley, Pharmacist
Director of Government Affairs

LRL/jel

RHODE ISLAND
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The Professional Society of Rhode Island Pharmacists

September 11, 1990

Senator John Chafee
567 Dirksen Senate Office Building
U. S. Senate
Washington, D.C. 20510

Dear Senator Chafee:

The intent of this letter is to reaffirm our support for changes in the Medicaid Program that will achieve equal access for Medicaid to fair prices for prescription drugs. Originally, this support was focused on Sen. Pryor's proposed legislation, the "Pharmaceutical Access and Prudent Purchasing Act of 1990"(S.2605).

We now understand that the Office of Management and Budget has proposed a variation of the Pryor proposal to be included in the budget reconciliation process, and a new adapted version of the Pryor legislation may be forthcoming.

We are gratified by the attention and progress that this issue has achieved in a relatively short period of time. We also hope that any new proposals will continue to include provisions to guarantee the best price for Medicaid from all drug manufacturers, continue patient access to needed medications, and restore fair and reasonable reimbursement to pharmacies.

In your position as a member of the Senate Finance Committee we hope you will continue to understand our concerns and add your support to this important change in the Medicaid system.

We thank you for your consideration.

Sincerely,
Denis Barton
Denis Barton
Executive Director

DB:dti

A2:CHAFEE.911

West Virginia Pharmacists Association
Suite 1002 Kanawha Valley Building, 300 Capitol St., Charleston, WV 25301
(304) 344-5302 • FAX: (304) 344-5316

September 12, 1990

The Honorable Jay Rockefeller
United States Senate
724 Senate Hart Office Building
Constitution Avenue & 2nd Street, NE
Washington, DC 20510

Dear Senator Rockefeller:

Pharmacist Sam Kapourales and I plan to attend your Subcommittee on Health for Families and the Uninsured hearing at 10:00 a.m., Monday, September 17, 1990. Your Subcommittee will have before it S.2605, introduced by Senator David Pryor (D-Ark.).

This proposed legislation is supported by this Association, which is a statewide organization founded in the 1890's and representing licensed pharmacists practicing in West Virginia. The following are the major reasons for our support.

The legislation provides a mechanism for Medicaid to secure reduced prices for drugs dispensed Medicaid beneficiaries. This will result in significant savings to West Virginia's Medicaid drug program.

S.2605 assures Medicaid beneficiaries access to a wide range of FDA-approved prescription drug products by permitting physicians to secure prior approval for drugs not on a state formulary. This assures beneficiaries of receiving the drug product their physician determines is necessary for their treatment.

The bill establishes a system of drug utilization review (DUR) that encourages pharmacists to counsel patients on the proper use of their medications and requires state Medicaid programs to implement a program to avert inappropriate patterns of prescribing and dispensing of drug products. This will improve the quality of health of Medicaid recipients, detect and reduce misuse and abuse of drugs, and reduce costs of West Virginia's Medicaid drug program.

S.2605 requires states to perform annual cost of dispensing studies for the purpose of updating professional fees paid pharmacists for providing services to Medicaid recipients. This provision will assure pharmacists that their cost of providing services will be reimbursed by Medicaid.

As you are aware, Senator Rockefeller, West Virginia experiences problems each year in funding its Medicaid program. Our Medicaid population is increasing and federal mandates are requiring more services be provided. West Virginia can only expect the need for state funding to increase in the future.

Pharmacists provide services to the medically indigent while, in some instances, waiting for several months for reimbursement. Some pharmacists have been forced to borrow money to pay manufacturers and wholesalers for medications dispensed patients because of the lack of Medicaid payments.

West Virginia pharmacists are paid a professional fee that is the second lowest fee paid by any state in the country. The fee has not been increased since you were Governor in 1981. And because of HCFA guidelines, our Medicaid program is proposing a 12 percent discount off average wholesale price as the basis of payment to pharmacists. This will be highest discount of any state in the country.

Many West Virginia pharmacists depend on both Medicaid and the UMWA Health Funds for economic survival. You are more aware than any United States Senator of the financial problems facing the Funds, and this Association commends you for your continuing efforts in solving these problems. The Funds problems coupled with proposed reductions in payments by West Virginia Medicaid can result in some pharmacists discontinuing services to Medicaid patients and retired coal miners. This would adversely affect access to health care to many West Virginians in certain areas of our state.

S.2605 offers savings to state Medicaid programs, improves health care to the medically indigent, and provides a system for fair reimbursement to pharmacists for their services.

You are respectfully requested to consider the above comments in reviewing the merits of S.2605. Your support of S.2605 will be appreciated by members of this Association.

Very truly yours,

Richard

Richard D. Stevens
Executive Director

RDS:msf

xc: WVPA Officers and Board of Directors

New Mexico
STATE AGENCY on AGING

224 East Palace Avenue, Fourth Floor, La Villa Rivera Building, Santa Fe, New Mexico 87501 (505) 827-7640

Garrey Carruthers, *Governor*
Stephanie J. FallCreek, *D.S.W.*, *Director*

90 SEP 26 AM 8:56

90 SEP 24 AM 4:23

September 18, 1990

The Honorable David Pryor, Chairman
U.S. Senator
Special Committee on Aging
G-31 Dirksen Bldg.
Washington, DC 20510-6400

Dear Senator Pryor:

This letter is to express support on the legislation requiring pharmaceutical manufacturers to provide the state Medicaid programs the same prices that private purchasers pay for drugs. I believe this is an extremely good idea which will allow Medicaid drug dollars to go a lot further to provide services for the elderly.

Again, I support this innovative legislation on behalf of seniors in New Mexico as well as nationwide, and appreciate your dedication and concern.

Sincerely,

STEPHANIE FALLCREEK, PH.D.
Director

SFC/cgm/s

xc: New Mexico Congressional Delegation

PREPARED STATEMENT OF STEPHEN W. SCHONDELMEYER

Thank you, Mr. Chairman, for the opportunity to provide input to the Subcommittee. I am Stephen W. Schondelmeyer, Associate Professor of Pharmacy Administration at Purdue University in West Lafayette, Indiana where I serve as Director of the Pharmaceutical Economics Research Center. My education and twenty years of experience and research have provided me with an understanding of the unique, complex, and technical issues related to third party reimbursement and pricing patterns within the pharmaceutical industry. Also, it was a pleasure to have served or the short-lived Prescription Drug Payment Review Commission, which was established under the now-repealed Medicare Catastrophic Coverage Act of 1988.

The goal of my prepared remarks this morning is to explore the major issues and options relating to legislative proposals regarding Medicaid drug prices and expenditures. I will attempt to answer three major questions:

1. Why are we dealing with legislation on Medicaid drug prices and expenditures?
2. What are the options for addressing the problem?
3. What constitutes sound public policy?

Lets begin by asking "Why are we dealing with legislation on Medicaid prices and expenditures?" It is not coincidental that consideration of this issue has come to the forefront of your agenda during the budget crunch on Capitol hill. Federal and State entitlement programs have been growing at a rate faster than the revenue sources that support them. This problem has been particularly acute with respect to the impact of growing Medicaid expenditures on state budgets over the past several years. States have been faced with a need to reduce the rate of growth in their Medicaid expenditures. They have examined and exercised a number of options including changes in: eligibility criteria for beneficiaries, scope of benefit coverage, utilization controls for beneficiaries and providers, and limits on reimbursement paid to providers such as hospitals, physicians, and pharmacists.

What has the growth rate been for Medicaid expenditures? Between 1982 and 1988 Medicaid total vendor payments grew from $29.9 billion to $48.7 billion. This represents a six-year growth of 62.8% and an average annual increase of 8.5%. Pharmaceuticals have been a small, but not insignificant, part of total Medicaid expenditures, growing from 5.4% in 1982 to 6.8% in 1988. In other words, pharmaceutical expenditures more than doubled from $1.6 billion in 1982 to $3.3 billion in 1988. In that time, the average annual growth rate for pharmaceutical expenditures of 12.9% was the highest of any of the major health services covered by Medicaid.

Drug expenditures have grown at a rate one and one-half times as fast as total Medicaid expenditures. The six year growth rate of 106% for drugs under Medicaid is nearly four times the growth rate of the Consumer Price Index (CPI–U, all items) which was 26.9% for the same period (1982–88).

What factors were responsible for this dramatic growth in Medicaid drug expenditures during the 1980's? Drug expenditure growth can be subdivided into a number of components, and the growth rate of each component can be examined to determine its relative contribution to total Medicaid drug expenditures. During the six-year period when total Medicaid drug expenditures increased 106%, the number of drug recipients increased 11.7% and prescription utilization (the number of prescriptions per drug recipient) increased 12.5% while the average prescription price to Medicaid increased 62.8% (Table 1). When examined further, the average prescription price can be broken down into drug product cost and pharmacists' fees. The drug product cost grew 86.5% while pharmacists' fees grew 15.1%.

From these findings one can conclude that, although a number of factors contributed to drug expenditure growth, drug product cost grew five to seven times more than any other single component of the Medicaid drug budget. The national Medicaid growth rate patterns described here are somewhat different than the studs of Medi-Cal expenditures sponsored by the Pharmaceutical Manufacturers' Association. Caution should be used in generalizing the atypical California Medicaid drug program to the broader national Medicaid experience.

Because of the limited revenue sources and the substantial growth in drug expenditures, Medicaid programs are now turning to the providers and producers of drug products to help manage growth in their drug program expenditures. A variety of methods for reducing drug expenditures have been tried. Some methods have been implemented without respect to need among the nations' poor citizens, such as limits on the number of prescriptions that can be filled in a given month irrespective of the patient's need. These approaches represent poor health policy and poor health care because they limit access through arbitrary restrictions, and not on the basis of need.

Many of the attempts at drug expenditure control by Medicaid programs focused on limiting the pharmacists' fees and drug product cost reimbursement. Pharmacists' dispensing fees in most states have been frozen for periods of three to ten years at a time. The 48 states providing Medicaid drug coverage averaged only three fee increases in the last ten years. The average annual increase in pharmacists' Medicaid fees was only 2.4%.

By 1989, three-fourths of the states had cut the drug product cost reimbursement to pharmacists by an average of 8.7% off the average wholesale price (AWP). These attempts at slowing drug expenditure growth succeeded in holding pharmacists' reimbursement to a growth rate which was nearly one-half the rate of growth in the general consumer economy. While these approaches have worked for controlling pharmacists' fees, it is now clear that growth in manufacturer's drug product cost cannot be controlled by limiting pharmacists' reimbursement. Remember that manufacturers' drug product costs during this period increased at more than three times the rate for the consumer economy and more than five times the rate of pharmacists' fees.

There are differences in the rate of growth among drug product prices based on the type of product and the manufacturer. A recently released report of the Health Care Financing Administration (*Manufacturers' Prices and Pharmacists' Charges for Prescription Drugs Used by the Elderly,* Health Care Financing Administration, June, 1990) determined that between 1981 and 1988 the average annual inflation rate for prescription drug prices was 9.1% for all products studied. Single source originator drug products averaged an increase of 8.6% per year while multiple source drug products averaged 9.3% increase per year. When multiple source drug products were divided into originator and non-originator manufacturers, the originators increased prices at an annual average rate of 10.8% while the non-originators (or generic manufacturers) increased prices at only 2.7% per year. These findings will be important later when determining how to target solutions to the source of the problem.

Clearly, targeted solutions are needed to address the primary source of growth in Medicaid drug program expenditures. Drug expenditure growth, *per se,* is not a problem as long as the increase in expenditures provide necessary and cost-effective therapy for Medicaid beneficiaries. New, more effective therapies are valued and needed in the prescription marketplace and not surprisingly will be more expensive when they arrive. However, the lack of resources to pay for all care needed by Medicaid beneficiaries and the continued growth of prices for existing drug products at rates faster than most other segments in the rapidly growing health care economy has brought Medicaid administrators and policymakers to look for new, more effective means for managing the rate of growth in drug expenditures.

This brings us to the second major question: "What are the options available to manage drug expenditure growth in state Medicaid programs? Many state programs have developed mechanisms for attempting to manage their drug expenditures.

The options for managing drug expenditures include: (1) establishing or revising formulary systems for managing drug coverage; (2) negotiating or requiring discounts from manufacturers; (3) providing improved drug utilization review; (4) establishing prior approval for drug products with a high potential for misuse; (5) providing improved administrative processing of prescription claims; (6) increasing use of low-cost multiple source drug products when therapeutic equivalence is established by the FDA Orange Book or similar means; and (7) limiting pharmacists' fees and drug product reimbursement.

More recently, revenue pressures at the state level have brought out a new round of legislatively-mandated cuts to the Medicaid program. Most states have squeezed out all they can from pharmacists' fees. Medicaid drug program administrators are now attempting to achieve additional savings through legislative or regulatory mechanisms which will require manufacturers to negotiate or provide discounted prices.

Some manufacturers have begun to offer discount or rebate programs, but only after the threat of Federal legislation came with the introduction of S. 2605 by Senator David Pryor (D-Ark) in the Spring of 1990. These manufacturer-offered discount programs are voluntary on the manufacturer's part, and place significant restrictions on the cost management options available to the Medicaid program, such as formulary systems and prior authorization programs.

Drug manufacturers' agreements at the state level are poor public policy for several reasons:

—First, every manufacturer has its own plan and forms of agreement, including special reporting and accounting methods. A state could end up with 15 to 30 or more different plans and increase significantly their administrative costs.

—Second, the plans are voluntary for the manufacturers, and will result in Medicaid programs becoming economically dependent on the manufacturers' continued cooperation. This situation could be leveraged by manufacturers to persuade state Medicaid programs not to propose or seek further management control tools over the prescription drug program.

—Third, it is very conceivable that manufacturers would offer voluntary discounts only to the largest states, leaving the smaller, but no less important markets, without access to such discounts.

Federal legislation with a standardized discount program and reporting system for all states would resolve each of these concerns.

An examination of price levels across different customer types has revealed that various purchasers pay widely varying prices for the same drug product (Prescription Drug Prices: Are We Getting Our Money's Worth?, Majority Staff Report of the Special Committee on Aging, United States Senate, August 1989, Serial 101–D). Purchasers may receive discounts in the marketplace for a variety of reasons. These discounts may range from a few percent to substantial price cuts in excess of 75%.

Bona fide discounts are offered by pharmaceutical manufacturers to a variety of purchasing organizations including: (1) organizations that purchase in large volume (e.g., buying groups or' HMOs), (2) non-profit and charitable institutions (e. g. hospitals'), (3) government agencies (e.g, state hospitals and prisons or the Department of Veterans Affairs), and (4) organizations that take direct delivery of product (e.g. large chain pharmacies or mail order firms).

The policy question that arises is "Should Medicaid be offered any of the discounts available to other purchasers in the marketplace?" With respect to volume, Medicaid programs pay for about 12% of the prescription dollars and 15% to 18% of the prescriptions in the retail marketplace. This would make state Medicaid programs the single largest payer for prescription drugs. In terms of charitable and non-profit status, state Medicaid programs are non-profit and serve more than 23 million persons from the nation's indigent population.

State Medicaid agencies are certainly government agencies and should qualify for any manufacturer discount given on such a basis. The only type of discount for which Medicaid would not qualify, on the surface, would be a discount for direct delivery. The state Medicaid programs do not actually purchase drugs directly from manufacturers, instead they contract with a network of pharmacies nationwide who in turn purchase drugs from the manufacturers. Most retail pharmacies, except for large chains, purchase their drugs through a wholesaler rather than direct from the manufacturer.

The drug distribution system provided to the nation's pharmacies by wholesalers is extremely efficient and adds very little additional cost (2% to 8%) to the drug distribution process. In fact, a number of drug manufacturers have wholesale-only distribution policies because it costs them more to operate direct shipping facilities for retail pharmacies. Of all types of drug price discounts that are offered by manufacturers, state Medicaid drug programs would appear to qualify for all except those based solely on direct delivery, and such discounts are normally quite small.

Since it can be argued that Medicaid should have access to volume, non-profit, and governmental discounts, and each of these types of discounts are typically greater than direct purchasing discounts', the issue of direct purchase discounts becomes moot. Given the size of the Medicaid program in each state and the fact that Medicaid qualifies for nearly all types of discounts typically offered in the marketplace, there is no reason the Medicaid program should not receive the "best price" of a given seller.

What constitutes sound public policy? First, the legislative approach chosen should have a high potential for "real economic" impact on Medicaid drug expenditures. For example, discounts are only relational in nature and may not have any real impact on expenditure levels unless both the PRICE LEVEL and the RATE OF GROWTH in prices are addressed in conjunction with defining the discount. We probably all have fallen prey to the 1discount shopper" mentality, which convinced us to buy something because it was 30% off, only to find that same item a week later at another store for less than the original sale price.

In other words, the net amount paid is the real issue, not the size or the amount of the discount. Also, the rate of growth of prices must be addressed if meaningful change in expenditures is to be achieved in the long run. A discount alone may provide a one-tinge notch or reduction in savings, but does not affect the rate of growth over time. Medicaid drug expenditures can be expected to double again in six years if the rate of growth in prices is not altered.

I am not saying that the U.S. government should establish or control drug prices as many other developed countries do, but government programs should not be afraid to establish the price they will pay in the marketplace as a major, if not the largest, purchaser of drugs. This expression of market power as a significant buyer in the marketplace should include establishing the price to be paid and the expected rate of change in price over time. Enactment of such price management tools for the Medicaid drug program is not different in its nature from the price management tools that Congress has already enacted for hospitals and physicians under the Medicare program.

I cannot think of another competitive marketplace where the largest buyer pays the highest price in the market, as does the Medicaid drug program. It would be irresponsible of state Medicaid programs and the Federal Government to remain a silent, passive buyer in the pharmaceutical marketplace. If a private business was purchasing 12% of the goods or services in a given marketplace, it would certainly not settle for paying the highest price in the marketplace, but rather would negotiate for discounts and the best price.

The Upjohn proposal is based on a flat fee per prescription plus a small percentage of the prescription price. This approach fails to recognize or address the primary issue of level and rate of price growth of drug products purchased by the Medicaid program. Simply by raising prices, manufacturers could cover the rebate cost and Medicaid would have a nominal rebate, but no realized savings. This rebate is couched more in terms of a value added tax on prescriptions than in terms of a lower price to a large buyer. Also, this approach would be somewhat regressive in that low cost prescriptions would pay a rebate that represents a high percentage of their total revenue while high cost manufacturers would pay a rebate that represents a smaller percentage of their total revenue. Such incentives appear to be in the wrong direction.

The Merck plan offered to various states as well as the new proposed legislation at the Federal level incorporates important features including a discount based on "best price" and a factor to adjust the rebate if the inflation in the Average Manufacturers' Price goes higher than the CPI. The Merck plan, however, does not include originator multiple source drugs in the discount program. There is no reason for Medicaid to start paying higher prices for a drug product after it goes off patent, which would be the case for "brand medically necessary" restrictive prescriptions unless these products are included in the Medicaid rebate program. Recall, also, that multiple source originator products had a higher average annual inflation rate than single source drug products, 10.8% versus 8.6% per year.

The Glaxo plan would establish a rebate based on the discount given to IPA-model HMOs. To suggest that IPA-model HMO prices be given to Medicaid is like recommending that Medicaid only pay the second highest price in the market. This basis for a rebate seems to ignore the fact that Medicaid is also a government agency and a non-profit program for the indigent. Purchasers in these two categories frequently receive discounts far greater than those given to SPA-model HMOs.

The first Pryor bill (S. 2605) calls for establishing a process which would have supported therapeutic interchange based on decisions made at the state and local levels. The threat of this type of legislation appeared to be the lever which initiated a dialogue with the pharmaceutical industry on means to contain Medicaid drug program expenditures. Although therapeutic interchange has not been widely implemented in open network, ambulatory environments, such as the Medicaid program; many hospitals and HMOs operate effective, high-quality formulary systems including therapeutic interchange. The opposition of many groups to therapeutic interchange and formularies within Medicaid appears to have been to forms of these programs quite different from what was actually proposed in S. 2605. Even though we may not be ready for a therapeutic interchange formulary in Medicaid, the concept should be evaluated as proposed in the second Pryor bill (S. 3029).

Pryor's legislative response (S. 3029) constitutes a very well "fleshed-out" approach to providing a meaningful drug expenditure tool to state Medicaid programs. Any Medicaid discount program should include not only single source drugs but also multiple source drugs as S. 3029 does. Several minor modifications to this bill should be considered, however. First, rather than establish a rebate by freezing the best price and indexing it to inflation, the discount should be governed by an inflation-indexed Average Manufacturer Price (AMP). Freezing the best price over time would only perpetuate the large price differentials in the pharmaceutical market today. Instead, allowing the best price to move while basing rebates on an inflation-adjusted AMP would allow the price differential gap to narrow, but contain expenditures by limiting the rate of price inflation.

The discount to state Medicaid agencies should be the amount by which the current AMP exceeds the lower of the following:

—(a) the manufacturer's "best price;"

—(b) 90% of the current AMP; or
—(c) 90% of the indexed AMP;

for each manufacturer, dosage form, and strength.

The indexed AMP is the AMP in effect on September 1, 1990 for each manufacturer's dosage form and strength and is updated by the Consumer Price Index for all items for all urban consumers. Manufacturers are free to establish their own price in the retail market. Manufacturers whose price increases are close to the CPI–U will pay smaller rebates, and those with price increases considerably above the CPI–U will pay larger rebates.

A provision in the legislation that makes good sense is the establishment of the Federal "look behind" program to encourage the dispensing of low-cost multiple source products when the physician has not issued a restrictive prescription for an originator multiple source drug. Unfortunately, the states have done a poor job of enforcing the "brand medically necessary" provision which is designed to promote use of lower-cost multiple source products. The originator product would still be able to compete for multiple source prescriptions based on price.

The final sections of S. 3029 contain provisions that should be retained in any version of this bill or related bills that move forward. The special studies prescribed in S. 3029 will provide much needed research and policy guidance for further improvements of Medicaid, and possibly a future Medicare, outpatient drug program. Demonstration projects would assess the value of drug utilization review programs, reimbursement of pharmacists' for cognitive services, and formularies and therapeutic interchange policies.

Finally, you should seriously consider the establishment of a Prescription Drug Policy Review Commission, which will serve functions similar to the Prospective Payment Assessment Commission and the Physician Payment Review Commission. A very modest investment would allow collection and development of data bases for drug policy research that can provide a solid base for future legislation regarding cost containment and Medicaid, or Medicare, outpatient drug programs.

In conclusion, legislation should be enacted to enable the state Medicaid programs to take advantage of their positions as large buyers in a competitive marketplace. Any such legislation should tie limited to making Medicaid programs active players in the market and should not attempt to regulate the market or its prices beyond the scope of the Medicaid program. Senate bill S. 3029 provides a good framework for building legislation to accomplish this goal. Any effective discount program should encompass single source and multiple source products and should include an inflation index to manage the rate of expenditure growth. Thank you, and I look forward to answering your questions and to working with the Committee in the short time frame remaining in this Congress to craft an acceptable solution.

Prepared Statement of Marsha Simon

Thank you for the opportunity to testify on the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990. Families USA supports this bill as a well-balanced mechanism for controlling excessive inflation in Medicaid drug costs, as well as for increasing access to needed prescription drugs for the very poor. This issue is important for all Medicaid recipients, but especially for low income seniors, who use three and one half times as many Medicaid prescription drugs as other Medicaid beneficiaries.

NEED FOR LEGISLATION

It is essential to ensure that the Medicaid program is getting its money's worth. It is unconscionable for states and the Federal Government to pay unreasonably high prices for drugs when other purchasers such as the Department of Veterans Affairs, hospitals, and HMO's have been able to negotiate price discounts with the drug manufacturers.

For 1991, Medicaid prescription drug costs are projected to be approximately $3 billion. According to the most recent HCFA data, Medicaid prescription drug payments from 1973–1985 rose at an annual rate of 11.8 percent, while prescription drug use rose only at an annual rate of 2.2 percent.

The Medicaid program is under pressure to do more with less. At the same time, need for medical assistance is growing. The cost of long term care is increasing, poor pregnant women and children have unmet needs and the elderly poor lack home and community-based alternatives to institutional care.

In response to high drug costs states have cut back their Medicaid prescription drug benefits. Many low income persons are forced to make choices between their prescription drug needs and other basic needs. S. 3029 will make it possible for Medicaid beneficiaries to receive the most appropriate drug at the best price possible. The bill does this by addressing two major problems: (1) staggering price increases for prescription drugs faced by the Medicaid program; and (2) current access problems faced by low income individuals who need prescription drugs.

STAGGERING PRICE INCREASES

Between 1981 and 1988, drug prices increased 88 percent. At the same time, the CPI for other products increased only 28 percent. In some states, the prescription drug portion of the Medicaid bill is higher even than payments for physician services. Overall, prescription drug costs are the fastest growing segment of the Medicaid budget, except for home health care.

State Medicaid programs are at a disadvantage when compared with consumers in other nations. Drug prices are, on average, 54 percent higher for the same drug in the United States than in European Economic Community nations.

LIMITED ACCESS

States are struggling to pay these staggering increases. Without S. 3029, their only option has been to cut back on drug coverage and accessibility. As a result, in many states Medicaid beneficiaries cannot get the medicines they need.

As of 1986, 48 states sponsored drug programs. Of those states, 22 charged copayments to beneficiaries. Eleven states limited the number of new prescriptions per month. Nineteen states excluded coverage of certain classifications of drugs. Twenty-eight states set reimbursement limitations. Oklahoma this year cut back its program from four to three drug prescriptions per month and South Carolina is considering dropping from three to one per month. In addition to these restrictions, some states have lengthy prior approval processes for doctor's prescriptions, limit the number of refills, and restrict which pharmacies may fill prescriptions for Medicaid beneficiaries. If a particular drug or entire class of drugs is not on a state formulary, it is completely unavailable to Medicaid beneficiaries in those states.

These kinds of Medicaid restrictions are having a harmful effect on the health of Medicaid beneficiaries. A study of New Hampshire's imposition of a three prescription limit per month found that Medicaid beneficiaries used 30 percent fewer drug products. The authors believe that these Medicaid beneficiaries did not get drugs they needed as a result of the limits.[1]

In the last five years, some states requested bids from manufacturers in an effort to lower prices by introducing competition into the drug marketplace. Until this legislation was first discussed, the drug companies refused to negotiate at all. Smaller purchasers, such as the Department of Veterans Affairs, HMO's and hospitals have been able to negotiate discounts. Medicaid on the other hand, is one of the largest purchasers of prescription drugs nationally.

IMPROVED ACCESS

This legislation requires Medicaid programs to cover all medically necessary drugs for Medicaid beneficiaries, either through a formulary or a streamlined prior approval process. Any manufacturer that successfully negotiates a contract with the state Medicaid agency would be guaranteed Medicaid coverage of their drug products. Negotiating a contract simply means offering the state the company's "best prices" for all the prescription drugs it wants Medicaid to cover. If manufacturers did not offer the "best price"—a 10 percent minimum and a 25 percent maximum discount—for all of their products in all of the states, none of their products could be included in any state's list of covered drugs. If a company is not willing to negotiate with Medicaid, then a patient could still get needed drugs if the physician received prior approval from the state Medicaid program.

The legislation prohibits Medicaid drug programs from excluding specific medically necessary drugs. Other restrictions would be less necessary as states could rely on savings from the manufacturers to control costs. To guard against manufacturers raising their "best prices" in the future, the prices would be indexed to the CPI and would be allowed to rise no further than general inflation each year. This will guarantee long-term savings and long-term improvement in access.

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[1] Soumerai, Avorn, Ross-Degman, Gortmaker, "Payment Restrictions for Prescription Drugs Under Medicaid," New England Journal of Medicine, 1987.

DRUG COMPANY ALTERNATIVES

In recent weeks, some major drug companies have voluntarily offered Medicaid discounts in an effort to demonstrate that this legislation is unnecessary. Merck and Pfizer have offered their "best price" discount to Medicaid. The Merck discount is the minimum allowed under S. 3029. Other companies have offered even smaller discounts.

It is important to understand the differences between the manufacturers' and the S. 3029 proposed discounts. The manufacturers' discounts would fail to produce reasonable prices to control inflation, or to discount prices for innovator multiple source drug products, and would fail to ensure adequate savings or improve access.

The manufacturer's contracts for the discounts are only for a year and there is no guarantee that these discounts will be offered again. The legislation, on the other hand, builds in penalties to ensure that the discounts are continued. It also includes a process for monitoring the "best prices" of the various companies to guarantee Medicaid the best price.

In addition, the manufacturer's proposals leave room for substantial increases in their prices over time. Even if a company promises their "best prices," no guarantee exists that these prices could not be raised over time. There is evidence that this happened to a similar process in the WIC program. After several years of rebates to states for infant formula, the drug manufacturers pushed prices high enough in 1989 to negate the value of the rebates. S. 3029 protects against this possibility by indexing the "best price" to the CPI.

There is another major loophole in the manufacturers' proposals. The manufacturers have made no proposal to discount innovator multiple source drug products (IMSDPs); that is, the original patented brand of a product that is now a multiple source drug. Medicaid incurs significant expenditures for these products and should therefore be able to negotiate discounts for them. S. 3029 would apply to both single and innovator multiple source drug products.

COST EFFECTIVENESS OF DRUG THERAPY

A 1987 study compared two states, one that had a drug payment program and one that didn't. The state with a drug program paid an annual average of $238.50 less in inpatient hospital care than the state that did not cover prescriptions, controlling for other variables.[2] In other words this state's prescription drug programs reduced total Medicaid expenditures. By increasing access to prescription drugs, S. 3029 may also create savings on other Medicare program expenditures.

S. 3029 will save the Federal Government an estimated $2.5 billion over five years. This savings should be used to help the Medicaid program address high priority unmet needs of Medicaid beneficiaries. One current initiative before the Congress that could be funded with these savings is S. 1942, the Medicaid Home and Community Care Options Act.

S. 2605, Prescription Pharmaceuticals Access and Prudent Purchasing Act of 1990

I would like to comment on one aspect of S. 2605. S. 2605, through a National Pharmacy and Therapeutics (P&T) Committee, creates a national list of therapeutically equivalent drugs. States must then cover at least one drug under each classification at a negotiated price. This is common practice for hospitals and HMO's. S. 2605 does not allow automatic therapeutic substitution, but requires communication between the physician and the pharmacist before a preferred drug could be substituted. If such communication is not immediately possible, Medicaid would allow pharmacists to dispense a three day supply of the prescription as written.

Some advocates initially believed this represented a decrease in access. We found this to be inaccurate, however. As described above, some states already exclude certain classifications, and some totally exclude certain drugs, without any provisions for an override. So in reality, the current situation in many states is more restrictive than it would have been under S. 2605.

While S. 3029 does not include the P&T Committee, it is simpler, has the potential of making more drugs automatically available, and saves more money. Therefore, as we supported S. 2605, we also support S. 3029. The National Pharmacy and Therapeutic Committee offers potential for providing physicians and pharmacies expert guidance on appropriate prescribing practices—an important goal that S. 3029 would reach by requiring a study on therapeutic equivalence and providing drug utilization review.

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[2] Lingle, Kirk, and Kelly, "Outpatient Drug Benefits for the Elderly and their Impacts on the Use and Costs of Health Care Services," Blue Cross/Blue Shield, 1987.

CONCLUSION

Mr. Chairman, this bill represents a rare opportunity to achieve savings and improve quality of care in the Medicaid program. National legislation is needed to ensure that manufacturers' best prices are offered to all state Medicaid programs.

The simple threat of this legislation has led manufacturers to offer some discounts. Their proposals represent much smaller savings, no direct increase in access, and no guarantee of continued savings. Without this legislation states will continue to see excessive inflation in drug prices, which will continue to restrict access to cost effective therapies for poor Medicaid beneficiaries.

We urge the Committee to adopt this legislation and to reinvest the savings in initiatives to meet high priority needs of Medicaid beneficiaries.

Prepared Statement of U.S. Representative Louis Stokes

Mr. Chairman, I appreciate the opportunity to testify this morning before your committee. Your record on examining issues of extreme concern to the American public is to be commended. By providing this forum today on the issue of prescription drugs and the Medicaid program, you once again show your concern that the health of all people, and in particular low-income and disadvantaged individuals, needs to be addressed. I also want to commend Senator Pryor and others who recognize the gravity of the problem, and have taken a leadership role in addressing the issue.

As a member of the House Appropriations Subcommittee on Labor-Health and Human Services-Education and chairman of the congressional Black Caucus Health Braintrust, I have through the years been very involved in improving the access to and quality of health care for Americans. I have been especially concerned about the health of minorities and the disadvantaged. This group of individuals experiences greater health problems and yet is the most unable to afford to pay for care. One aspect of health care that has been found to be extremely costly, yet a necessity to maintaining good health, is prescription drugs.

As you know, the rising cost of prescription drugs has been a concern of Congress for some time. Previously unsuccessful bills have been introduced as a means of reducing the burden facing not only the poor, but the elderly and all groups, for whom prescription drug costs are accelerating beyond their control. During the last session of Congress, one of the most controversial aspects of the Medicare catastrophic act was the prescription drugs provision. This year, we find controversy surrounding S. 2605, the pharmaceuticals access and prudent purchasing act of 1990, and the office of management and budget proposal to utilize "therapeutic drug substitution" in the Medicaid program. As a result of the debate that these measures have provoked, there is also now before us another bill—S. 3029—that speaks to the issue of reducing Federal and states Medicaid prescription drug costs.

Mr. Chairman, I agree with my colleagues and others that something needs to be done to address the high costs of prescription drugs, and in particular the enormous costs our Nation and states pay to the Medicaid program. We require health care providers who participate in Medicaid and Medicare to accept certain requirements as a condition of participating in the program, so why should we accept less of any other group.

However, any approach we select must take foremost into consideration the health consequences to the patient. This includes the consequences they suffer because many of the products necessary to treat their illnesses are not affordable under the Medicaid program.

I know that there is no quick or easy solution to this problem. It is but part of the overall dilemma facing our Nation's health care delivery system, whose costs are skyrocketing everyday. But I am confident that we have the wherewithal to come to some solution on this issue. What it is going to take, however, is that everybody involved from the medical, pharmaceutical and patient advocate communities be willing to come to the table and give something to the solution. My staff has been working with many of the parties involved in this regard. It won't be easy, but it must be done.

Mr. Chairman, the health of all Americans should be first and foremost in our minds. We must do all that we can to educate our poor and elderly to practice preventive health care so that they may need less requiring of prescription drugs for their health. In the meantime, let's proceed with extreme caution to avoid jeopardizing their health for the sake of achieving budget savings.

I look forward to working with everyone involved to achieve a remedy to this pressing problem. Again, thank you for the opportunity to speak on this issue.

Prepared Statement of Judith L. Wagner

STRATEGIES FOR CONTAINING MEDICAID PRESCRIPTION DRUG COSTS

Mr. Chairman, I am happy to be here today to provide testimony on approaches to containing Medicaid prescription drug expenditures. At your request, OTA reviewed the evidence on prescription drug cost containment with particular emphasis on the implications of cost reduction strategies for pharmaceutical research and development (R&D) and the new technology it produces. As you know, OTA is currently engaged in a study of the costs of pharmaceutical R&D. My remarks today draw partly on what we have learned so far from that assessment, but most of my statement today is independent of that study.

The need for effective cost containment of Medicaid prescription drug expenditures is growing. Between 1980 and 1989, Medicaid payments for prescription drugs increased 180 percent, from $1.3 billion to $3.7 billion, compared to an increase of 134 percent in total Medicaid payments during the same period (see table 1). By 1989, Medicaid spending on prescription drugs represented slightly less than 7 percent of total Medicaid payments. Although this is still a modest proportion of total Medicaid expenditures, whenever opportunities exist for cost control they should be seriously considered.

Other impacts of cost control must also be considered, however. Medicaid program cost savings must be weighed against effects on Medicaid patients' access to needed medicines and on the flow of new pharmaceutical products in the future. These three kinds of impacts—cost, access, and innovation—provide the basis for evaluating the worth of a particular strategy, and I will use this set of criteria to examine some broad cost containment alternatives for Medicaid prescription drugs.

First, it is necessary to distinguish between two parts of the product life-cycle of a particular prescription drug. When a unique drug entity has been developed and first approved for marketing by FDA, its originator typically enjoys a period of monopoly while it is protected by patents. During this period, which may last from 7 to 15 or so years after FDA approval, the drug is a *single-source product* marketed under a brand name. All prescription drugs have generic names assigned to them, but during this period the brand name and the generic name are interchangeable.

Once the patent on a drug has expired, other firms who have received FDA approval may manufacture and sell generic copies of the name brand drug. At this point in its life-cycle, the compound becomes a *multi-source product,* and the potential for price competition increases. Before 1984, few drugs whose patents had expired were subject to competition from generic manufacturers because FDA subjected all applications for marketing to the same standards of evidence. Potential manufacturers of generic drugs found it very expensive and sometimes technically infeasible to conduct the necessary clinical trials on a drug that was "bioequivalent" to a name brand product already on the market. The Drug Price Competition and Patent Term Restoration Act (P.L. 98–417), which permitted FDA to expedite the approval process for generic versions of brand name drugs already found to be safe and effective, ended that situation. Today, many drugs, particularly those with large markets, have a generic competitor prepared to compete as soon as the patent expires.

All 50 States have drug product selection laws that either require or permit pharmacists to substitute less expensive generic drugs for the prescribed brand name drug so long as it is not expressly prohibited by the ordering physician. The physician can prohibit generic substitution by indicating on the prescription pad that the name brand drug must be dispensed by the pharmacist. Two recent studies have shown that a strong predictor of the extent of generic substitution in a State is the amount of extra work required of the physician writing the prescription to insist on the brand name (1,8).

Data on the relative size of the multi-source and single source Medicaid market are difficult to come by, but a study conducted by New York State's Medicaid Division in 1989 found that 47 percent of prescription drug claims and 65 percent of payments for the top-selling 1,500 drugs were for single-source drugs (table 2). The top 1,500 drugs accounted for 78 percent of all prescription drug claims and 91 percent of all payments, so even if none of the others are multi-source drugs, the single-source drug market comprises at most 58 percent of all claims and 68 percent of all payments[1] (2). The remaining 42 plus percent of claims are for prescriptions that could be filled with either a name brand product or a generic equivalent. The multi-source market share is likely to grow in the next five years as well, because a large number of patents on high selling single-source drugs is due to expire in that time.

The multi-source market is typically highly price competitive. Generic producers of multiple source drugs price their products well below the originator's name brand version. Indeed, anecdotal evidence about specific high-selling compounds indicates that the lowest generic price can be one-half to one-tenth as high as the price of the originator's name brand product. The potential for Medicaid savings through generic substitution is clear.

Both States and the Federal Government have recognized the importance of generic substitution for multi-source drugs as a cost control vehicle. Since 1987, the Federal Medicaid program has required States to document that their expenditures for multi-source drugs do not in the aggregate exceed 150 percent of the least costly generic equivalent that can be purchased by pharmacists in reasonable quantities (3). A loophole in that requirement, however, is that the upper limit does not apply to prescriptions on which the physician has certified in his or her own handwriting that a specific brand is "medically necessary" for a particular Medicaid recipient. High rates of physician "override" of generic substitution and low enforcement of the override requirement at the pharmacy can undermine the potential cost savings from generic substitution.

To what extent has generic substitution occurred in Medicaid? We could find no national Medicaid data on rates of brand name vs generic prescribing for Medicaid. For the country as a whole (Medicaid and non-Medicaid), about 50 percent of all prescriptions filled in 1989 for the top 24 multi-source drugs dispensed in community pharmacies were filled with the originator's brand name drug (10). Two State Medicaid agencies shared the results of their own special studies of generic prescribing with OTA. The first, New York State, found that over 63 percent of all Medicaid claims for multi-source drugs were filled with brand name drugs. (table 2). Those brand-filled claims accounted for 81 percent of the total payments for multi-source drugs. The second study, conducted in Florida, found that almost 40 percent of prescriptions for multi-source drugs were written with a physician's brand "override" and filled with the originator's brand (17). Out of a State-wide 6-month prescription drug budget of approximately $87 million, these "override" prescriptions accounted for $35 million in expenditures. On the basis of that study, Florida's Medicaid program issued a rule this year mandating the use of available generics and essentially refusing to pay for name brand drugs when generic equivalents exist.

We do not know how representative the New York and Florida experiences with multi-source drugs are, but these studies suggest that opportunities for reaping the cost-containment benefits from price competition engendered by the Drug Price Competition Act have not been fully seized by Medicaid.

How does cost containment through greater generic substitution affect the other two criteria for judging cost-containment: access and innovation? FDA's regulatory process is also designed to assure that generic equivalents of name brand drugs meet standards of equivalence that maintain the quality of generic drugs on the market. Recent efforts at FDA have been made to strengthen that regulatory effort. It seems reasonable, then, to presume that unless there is a compelling medical reason for an exception, prescribing FDA approved generic drugs will not affect the quality of care offered to Medicaid recipients. And, since about 50 percent of the leading multi-source drugs dispensed in community pharmacies today are filled with generics, increasing generic prescribing in the Medicaid multi-source drug market does not imply a double standard of health care.

Generic substitution also can be expected to have minimal impacts on pharmaceutical R&D or innovation. Reducing the share of the market for the originator company's brand name certainly takes revenue away from pharmaceutical firms that have been innovative, but today's investments in R&D are governed by the future stream of returns expected from the drugs that may be discovered and developed as a result of R&D. These expected returns extend many years out into the future and must be discounted back to their present value to the firm. Because generic competition occurs at the end of a drug's product life-cycle, lower expected returns many years in the future when patents expire are much less important to the R&D decision than are changes in market returns when a drug is first introduced.

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[1] Claims are not the same as prescriptions, but we have no reason to believe that the two measures of volume would be distributed differently between single source and multiple source drugs.

Some pharmaceutical companies have argued that reductions in revenues today, regardless of their source, reduce R&D budgets today. But there is no evidence to suggest that cost cutting in pharmaceutical firms would focus on R&D as opposed to other elements of cost, *provided that the potential future returns to investments in R&D are not much affected.* Indeed, the profitability of expenditures for marketing multi-source drugs might decline, which would lead a rational firm to reduce marketing expenditures for those products.

To summarize, strategies to squeeze the maximum possible savings from the use of FDA approved generic substitutes for brand name multi-source drugs offer sizable savings for Medicaid without hurting competing objectives of access and innovation. Florida has recently taken the lead by refusing to pay for brand name drugs when a generic equivalent is available. Other strategies, such as providing education or incentives to physicians, pharmacists, or patients to raise rates of generic substitution are also possible, but the effectiveness of particular strategies has not been studied in detail and we can say very little about what would work best.

Now, turning to the single-source drug market: the 50 to 60 percent of prescriptions for which direct price competition is not at present a feasible cost-containment strategy. In the New York State Medicaid program, single source drugs accounted for between 65 and 70 percent of expenditures in 1989. Medicaid agencies have a long history of cost-containment measures that affect single-source drugs, including the following:

- Requirements for copayments by enrollees—About 22 States require the enrollee to pay a part of the cost of the drug, but in most states with this provision the copayment is $1.00 or less. Federal law prohibits States from requiring children or pregnant women to share in the cost of Medicaid services, including drugs.
- Maximum payment limits for all drugs dispensed—Virtually all States pay a fixed dispensing fee and an amount to cover the ingredient costs. The median dispensing fee in 1989 was $3.65 (11). Payments for the cost of ingredients are typically limited to the average wholesale price of the drug, with some States discounting payment rates off the average wholesale price by 5 to 10 percent.
- Dispensing Restrictions—These include restrictions on the amount of a drug that con be dispensed at one time or on the number of prescriptions that can be reimbursed in any month. Limits on prescription size are intended to prevent hoarding or inappropriate drug sharing by enrollees, whereas limits on the total number of prescriptions are intended to discourage indiscriminate prescribing by physicians and drug use by recipients.
- Drug Utilization Review—Almost all Medicaid programs claim to have some kind of a program to review the utilization of prescription drugs, but most are retrospective systems designed to detect fraud, not to provide therapeutic guidance. In the past few years, eleven states have adopted more formal therapeutic drug-use review programs that are typically administered by private contractors.
- Restrictive Formularies—These are lists of drugs that are approved for payment by Medicaid. Claims for prescription drugs that are not on the formulary are denied payment by the State Medicaid program. About 22 States use restrictive formularies today.
- Prior Authorization Certain drugs may be identified as being covered only with the prior approval of the State Medicaid program. This approach is used most often with very expensive drugs or with drugs which are most appropriate after treatment failure with alternatives.

Several studies have examined the effects of particular strategies. Unfortunately they all have flawed research designs, so conclusions must be tentative. The use of copayment requirements has consistently reduced drug program expenditures (12,14,15), but none of the studies of copayments examined the impact on overall use of Medicaid services or on total program expenditures. Since copayment discourages consumers from filling prescriptions, negative impacts on health outcomes could also ensue, but possible effects in that area have not been examined.

Findings on the impact of restrictive formularies on Medicaid drug program costs are equivocal, but so far, this approach has not been found to yield substantial savings in drug program or total Medicaid costs (9,13). It is important to note, however, that no study to date has provided an adequate research design for examining the cost impacts of formularies. The problem is that States with high Medicaid costs might be the most likely to turn to formularies for cost-containment, thus creating an observed correlation between high costs and the existence of restrictive formularies. It is difficult to design studies that can control for the two-way causal relationship between costs and formularies. The most recent and comprehensive analysis of the impact of Medicaid formularies on Medicaid costs, which found no significant impacts on total costs:, is currently being replicated by researchers at the Congressional Budget Office, and preliminary results suggest that the original study should be interpreted with caution (7).

Any cost containment strategy that affects the market for single source drugs should be evaluated carefully for potential impacts on innovation. Strategies that put particular burdens on new drugs entering into the market are likely to have a larger negative impact on R&D and innovation. Closed formularies that require an application process before a drug can be prescribed for Medicaid patients can add a measure of uncertainty and delay which, if the size of the Medicaid market is large enough, could dampen R&D. The existence of a closed formulary does not in and of itself imply that uncertainty and delay will be high, but how the formulary is administered is critical. In an ideal world, important new drugs would always be approved quickly with minimal red tape or documentation requirements, and trivial or marginal drugs would never be approved. Were formularies consistently to operate this way, they could actually enhance the effectiveness of innovation by sending appropriate signals to managers of pharmaceutical R&D about the kinds of drugs that will be rewarded. The ideal is difficult to achieve, however.

OTA reviewed the evidence on delays in approvals of new drugs in States with restrictive formularies. A study of delays in Medicaid formulary approvals for new drugs introduced between 1975 and 1982 in six states with restrictive formularies found that the average delay in approval time for those drugs that actually were accepted onto the formularies ranged from about 1 to 4 years after the drug had been approved for marketing by FDA (5). A recent update of that study, which examined nine states over the period 1979 to 1984, found delay times that were similar to those found in the earlier study (4).

To get a sense of Medicaid formularies have handled important new drugs that have been introduced into the market within the past three years, we analyzed three new products; two were developed for AIDS patients, and the third, Prozac, is the first product in a new class of antidepressant (table 3). Virtually all States have adopted the three drugs, but several States require prior &approval before they are dispensed. Approval of Retrovir (AZT) took as long as two years in some States.

Have formularies as they have operated up to now hindered innovation in new drugs? We are confidant that the answer is no, for several reasons. First, Medicaid as a whole accounts for approximately 13 percent of all spending for prescription drugs in the United States,[2] and the U.S. market for prescription drugs is only about 25 percent of the total world market. Since only 22 states have such formularies, and they are not all administered with a great deal of delay and uncertainty, the overall impacts of such restrictions on potential returns from new drug development are minimal. Depending on how it was implemented, however, a national Medicaid formulary might well have a stronger negative effect on investment in R&D.

Any cost-containment strategy that sets up hurdles for a new drug to overcome will alter its stream of returns and send signals of uncertainty about future returns from today's investment in R&D. The strength and impact of these signals will depend on the precise structure of the strategy and the size of the market covered by the payer. In the United States, Medicaid is the largest third party payer for prescription drugs, so any concerted national Medicaid policy should be constructed carefully to minimize such effects. The ideal strategy would be one that embraced important new therapies with virtually no delay and that weeded out worthless therapies, with no mistakes in between. Achieving such a strategy in practice may be impossible, however. In the meantime, there is real opportunity for immediate savings to Medicaid, with virtually no harmful effects on either beneficiary access or innovation, through cost containment aimed at multi-source drugs.

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[2] According to unpublished data supplied by HCFA, total national spending on prescription drugs in 1988 was approximately $27.1 billion (6). Medicaid spending in 1988 is shown ill table 1.

Table 1.—MEDICAID PRESCRIPTION DRUG PAYMENTS: TOTAL AND AS A PERCENT OF TOTAL MEDICAID PAYMENTS, FISCAL YEARS 1972–1989

Fiscal year	[A] Total Medicaid payments (in millions of dollars)	[B] Total Medicaid prescription drug payments (in millions of dollars)	[B] as a percent of [A]
Fiscal year ending June 30:			
1972	6,300	512	8.1
1973	8,639	609	7.0
1974	9,983	713	7.1
1975	12,242	815	6.7
1976	14,901	940	6.7
Fiscal year ending September 30:			
1977	16,239	1,019	6.2
1978	17,992	1,082	6.0
1979	20,472	1,196	5.8
1980	23,311	1,318	5.7
1981	27,204	1,535	5.6
1982	29,399	1,599	5.4
1983	32,391	1,771	5.5
1984	33,891	1,968	5.8
1985	37,508	2,315	6.2
1986	41,005	2,692	6.6
1987	45,050	2,988	6.6
1988	48,710	3,294	6.8
1989	54,500	3,689	6.8
Compounded Annual Change: 1972–1979	16.3%	12.9%	
Compounded Annual Change: 1960–1989	9.9%	12.1%	

Source: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, Division of Medicaid Statistics, unpublished data provided by T. Parker, Aug. 29, 1990.

Table 2.—EXPENDITURES AND CLAIMS FOR TOP 1,500 PRESCRIPTION DRUGS [1] IN 1989 NEW YORK STATE MEDICAID

[All numbers in thousands]

	Dollars paid	Percent of total drug spending	Number of claims	Percent of total drug claims
Top 1,500 Drugs	$448,667	100.0%	19,573	100.0%
Multi Source Brand	127,665	28.5	6,607	33.8
Single Source Brand	291,681	65.0	9,155	46.8
Multi Source Generic	29,321	6.5	3,810	19.5

[1] The top 1,500 drugs made up 91.1% of all drug expenditures and 77.6% of all claims in 1989.

SOURCE: New York State Department of Social Services, Division of Medical Assistance, Bureau of Ambulatory Services, Inpatient Care and Contracts, unpublished data, 1990.

Table 3.—MEDICAID FORMULARY STATUS OF THREE RECENTLY APPROVED DRUGS IN TWENTY STATES WITH RESTRICTED FORMULARIES: SEPTEMBER 1990

Date of FDA approval	Cytovene^{R} (Cancyclovir) June 23, 1989	Retrovir^{R} (AZT tablets) March 19, 1987	Prozac^{R} (Fluoxitene) Dec. 29, 1987
Alabama	Yes	Yes	Yes
Arkansas	PA	PA	PA
California	Yes	Yes	PA
Colorado	Yes	Yes	Yes
Georgia	PA	PA	Yes
Hawaii	Yes	Yes	Yes
Illinois	Yes	Yes	Yes

Table 3.—MEDICAID FORMULARY STATUS OF THREE RECENTLY APPROVED DRUGS IN TWENTY STATES WITH RESTRICTED FORMULARIES: SEPTEMBER 1990—Continued

Date of FDA approval	Cytovene^{R} (Cancyclovir) June 23, 1989	Retrovir^{R} (AZT tablets) March 19, 1987	Prozac^{R} (Fluoxitene) Dec. 29, 1987
Kansas	Yes	Yes	Yes
Kentucky	PA	PA	Yes
Michigan	Yes	Yes	Yes
Minnesota	Yes	Yes	Yes
Missouri	PA	PA	PA
Mississippi	Yes	Yes	Yes
New York	Yes	Yes	Yes
Ohio	Yes	Yes	Yes
Oklahoma	Yes	Yes	Yes
Tennessee	Yes	Yes	Yes
Virginia	Yes	Yes	Yes
Washington	Yes	Yes	Yes
West Virgiria	PA	PA	PA

Key:
Yes—Included in state's Medicaid formulary
PA—Available with prior approval only
R—Registered Trademark

Source: First Data Bank, Inc.

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Prepared Statement of Gail R. Wilensky

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today to discuss the issue of Medicaid prescription drug costs. We have taken a hard look at the problem. I would like to share some of our thinking with you today.

BACKGROUND

Prescription drug coverage is an optional service under Medicaid. Still, all States have taken advantage of this option and provide some type of benefit. States have broad discretion about which FDA-approved drugs they will cover; how much, within Federal upper : limits, they will pay pharmacists; and what other restrictions they will place on drug use, such as prior approval of brand name drugs. About 35 States have relatively open formularies and reimburse for almost all FDA-approved drugs. The other States have more restrictive formularies, but few, if any, parallel the closed formularies used by some HMOs or hospitals.

We estimate that expenditures for Medicaid prescription drugs will be $4.4 billion in FY 1990, and $8.2 billion by FY 1995. These represent minimum outlays; they do not include prescription drug expenditures incorporated in inpatient hospital claims or nursing home reimbursement rates. As we consider Federal changes in prescription drug payment, I believe it is important to understand the prescription drug market. At least relative to much of health care, we have a functioning market.

Nearly 60 percent of all prescription drugs are paid for out of pocket. Medicaid, Medicare (for selected drugs and settings), HMOs and occasionally traditional insurance pay for the 40 percent of drugs covered by third party payments. As a result, retail prescription drug prices are set under something that resembles a traditional competitive market with supply and demand setting the "price." There are at least two complications:

- Patents, granting a 17-year monopoly to new drugs (sole-source drugs) as to other inventions, are used to encourage the R&D effort needed to develop new products. Manufacturers invest substantial resources to develop new drugs. If competitors could copy a new drug immediately without such investment, a strong disincentive would exist for the R&D necessary to develop drugs.
- Consumers rely on the decisions of physicians who write the prescription. While I believe physicians often take into account financial concerns, this process distances the payor-patient, from the decision about what and how much to purchase.

Even with these complications, we must use care to protect the thriving R&D associated with prescription drugs. And we must be concerned for what is one of our most internationally competitive industries.

As a result, different policies may be appropriate for different classes of prescription drugs. It has been estimated that in Medicaid, about 37 percent of drug spending is for sole-source drug ingredient costs, and 26 percent for multiple-source drugs. About 10 percent is spent on over-the-counter drugs and another 27 percent is accounted for by dispensing fees to pharmacists. Almost two-thirds of the 26 percent spent on multiple-source drugs is for brand-name drugs.

PURDUE STUDY

After lagging behind inflation in the 1970's, manufacturers' drug prices have increased over the past decade at three times the rate of general inflation.

A recent study conducted by Purdue University under contract to HCFA found that from 1981 to 1988, a total of 104 drug entities (11.4 percent of all drug entities) accounted for 80 percent of expenditures by the elderly. Although there are differences in drug used by the elderly and Medicaid recipients, this study's findings are illustrative. In comparison the average prescription price nearly doubled for these drugs, from $10.73 to *$20.78*. Prices of the ingredients charged to pharmacies more than doubled from $6. 94 to $15.29, and pharmacies' margins increased from $3.79 to $5.48.

The report makes clear that although pharmacies' margins have declined as a percentage of retail prescription price (from 35.3 percent to 26.4 percent), even after taking inflation into account, pharmacists' dollar margins have increased $0.33 on an average prescription. The average pharmacy margin per unit for single-source prescriptions was consistently higher than the average margin per unit for multiple-source prescriptions.

In addition, from 1981 through 1988, the average annual drug ingredient price has increased as a percentage of the retail prescription cost. On an average prescription, the cost of the product dispensed increased $8.35 during this period. Even taking inflation into account, the ingredient price for the average prescription increased by $4.56.

The patent process provides a temporary (potentially 17 years) monopoly to manufacturers who obtain a patent on a new single-source drug. Several year ago, in recognition of the effect of the drug approval process in reducing the actual years of patent protection available after approval, the Congress enacted additional protection for drugs through the Drug Price Competition and Patent Term Restoration Act. This law also accelerated the availability of generic substitutes for many off-patent drugs.

CURRENT SAVINGS EFFORTS

Let me give you some examples of recent State efforts to control prescription drug costs.

- The State of Georgia recently enacted legislation that will require manufacturers to offer discounts for drugs on the State formulary.
- Kansas relies on a restricted formulary and drug utilization review, but has had limited success in getting bids for drugs. The State is considering a multi-State buying group as an alternative approach. The State legislature recently passed a law requiring an open formulary, but the effective date was delayed two years.
- California has a restrictive drug formulary, a policy of generic substitution, a rigorous prior authorization process, and a maximum allowable ingredient cost program. A study completed in April 1990 by Systemetrics/McGraw Hill for the PMA found that in spite of those program elements, Medi-Cal drug program expenditures climbed an average of 15 percent per year since 1984. California is one of the States that has signed a contract with Merck and Co. for discounts.

Also, we are hearing almost daily that company "X" has signed an agreement with State "Y" granting discounts. We attribute this to the pressures being felt by the industry from our—the Administration's and Congress's—efforts.

Despite these successes, we are concerned that Medicaid continues to pay substantially more for drugs than many hospitals and HMOs, other Federal agencies such as the Department of Veterans' Affairs, Department of Defense for the military and CHAMPUS, and even by some open-ended IPAs or PPOs. We are encouraged by recent indications that some pharmaceutical companies are willing to provide to Medicaid discounts similar to those given to direct providers. It is only right that the poor, elderly, and disabled who are dependent on medical assistance should receive the lowest price for needed medicines. We support continued State efforts to reduce costs through prudent management of their programs.

HCFA PRINCIPLES FOR PRESCRIPTION DRUG REFORM

First, growth in spending for prescription drugs under Medicaid makes proposals to achieve savings attractive, appropriate, and even necessary. At the same time, we must also assure that any reforms to current Federal reimbursement for prescription drugs do not harm Medicaid recipients, for instance by causing mare physicians or pharmacists to decline to treat Medicaid patients.

And we must always recognize that there are 50 State programs, not just one Federal program. We believe that any changes should encourage States to achieve savings that build on their current best practices, while at the same time encouraging further innovation.

Based on these principles, I'll first state what we're *not* for, and then describe what we believe *can* work.

We believe that any Federal proposal involving—requiring or encouraging—therapeutic substitution, is an unacceptable interference with the physician-patient relationship. Such a mandate could have severe negative consequences on the quality of health care Medicaid recipients receive since there are thousands of drugs' and substitution will vary by diagnosis.

Proposals involving therapeutic interchange hope to introduce added competition into the sole source drug market by characterizing some sole source drugs as substitutes for each other (at least in certain circumstances). I understand the logic but would note that by their very nature these drugs are chemically different. For individuals, substitution may have significant unintended therapeutic consequences.

We would also strongly question proposals that allow a pharmacist to dispense only a limited supply of prescribed medication while he/she tries to contact the physician. This may interfere with appropriate access to needed medicines. Poor and elderly Medicaid recipients may not return to get refills of needed medication due to transportation problems, or they may incorrectly interpret the limited supply as sufficient if symptoms ease or cease.

Again, we must be careful not to interfere with market forces in ways that might result either in inflated drug prices or prices so depressed that manufacturers no longer invest in new product research. Concurrently, we need to ensure competition, encourage manufacturers to offer Medicaid their best price, safeguard States' prescription drug coverage options, and assure access to needed medicines for Medicaid recipients.

We also must ensure that any changes to current Federal reimbursement methods for prescription drugs do not lead to unintended or mandated program expansions, such as requiring States to increase payments for pharmacists.

Finally, we should resist the temptation to endorse changes with only short-term savings; reforms should be designed so savings now can be built upon in the future.

Some proposals call for the establishment of mandatory drug utilization review programs in the overall cost containment effort. While mandatory drug use review programs might appear to offer potential savings, there is a risk that such a highly specific Federal mandate could stifle individual State creativity in tailoring drug use review to the local situation. Furthermore, related administrative difficulties and costs must be recognized.

A good first step would be to study existing State drug utilization review programs and disseminate the findings in a "best-practices" guide for use by other States.

OPTIONS UNDER HCFA CONSIDERATION

We are considering a combination of options for an appropriate prescription drug policy including:

- Limiting Federal reimbursement for drug ingredients to the manufacturers' best price, within limits, to ensure continued savings and manufacturer participation.
- Enforcing limits on the growth rates and amounts of Medicaid pharmaceutical reimbursements.
- Better enforcement of existing requirements for generic dispensing, through increased auditing of payment limits, tightened use of "brand medically necessary" language and focused review in certain target areas.
- Encouraging States to adopt tighter payment limits for name brand drugs when generic equivalents are available.
- Fostering a competitive bidding process at the State level for a limited number of high volume multi-source drugs with wide price differentials and assurance that the drugs from winning bids are available to pharmacies throughout the State.

Additionally, HCFA could conduct research on the cost-effectiveness of certain high volume, high cost drugs, and test and evaluate alternative strategies such as mail order prescriptions, and best practices in State drug use review. These activities would supplement our review of how interim policies work in developing permanent policies.

CONCLUSION

In closing, let me reiterate our belief that any proposal to address Medicaid prescription drug costs should assure a balance among costs savings, appropriate Federal-State roles, access to medically necessary drugs for Medicaid recipients, adequate payment for pharmacists' services and the protection of the physician-patient relationship. We earnestly want to work with the Congress, the pharmaceutical industry, and health care providers to effect changes that will constrain increasing drug costs in the Medicaid program.

Thank you for the opportunity to discuss this important issue. I would be happy to answer any questions you may have.

Attachments.

RESPONSES BY MS. WILENSKY TO QUESTIONS SUBMITTED BY SENATOR PRYOR

Question No. 1. You indicated at the hearing that HCFA could support the development of a "minimum-type discount and maybe a maximum-type discount also on a best price so that you do not try to put the industry in a position that might be regarded as too extreme." You also stated support for some type of indexing.

My bill, S. 3029, calculates the discount based on the manufacturer's "best price" in the market as of September 1, 1990 (indexed to the CPI), but caps manufacturer rebates at 25% of total ingredient cost. Would you consider this approach to be too extreme? Could you be specific about how HCFA would propose to utilize a "best price" approach with indexing? How would the growth rate of expenditures be limited in the HCFA plan?

Answer. It is very difficult to measure "extreme" in this area. There are alternative means to achieve the same goal that would allow more flexibility in the market and assure savings at the same time.

While HCFA does not yet have a specific proposal, the approach we are considering would measure a manufacturer's "best prices" across the company's product line, and vary rebates for that manufacturer if the "best prices" on average, rose too quickly over time. We also believe some "best price" should be defined with both a minimum and maximum discount, perhaps phasing in the maximum discount to allow manufacturers time to adjust to the reduced payment. Industry representatives propose phasing in at levels of about 10 percent in the first year to 20 percent after three or four years.

We would prefer to measure across a product line because we can never be sure of what might cause a particular product's price to rise. Our approach would allow flexibility for these circumstances, while assuring that a manufacturer could not systematically increase "best prices" across the product line in a manner that would erode savings to the Medicaid program. In addition, there must be a policy to take into account unusual circumstances—with the onus on the manufacturer to prove the exceptional circumstances.

We do maintain that sole source drug prices cannot be allowed to rise as they did in the 1980's. As such, we believe that if a manufacturer's prices, across the product line, were to rise too much more than the CPI or M/CPI, added rebates should be required.

Question No. 2. Without some form of Federal legislation, smaller states are concerned that they lack the clout to force manufacturers to sign "voluntary" rebate agreements with them. The states, the AMA, OMB, and even the experts seem to agree that a Federal approach is needed. Your testimony seemed to imply that you see a role for the Federal Government in this area. Is this true, and can you be specific about what role you foresee? In addition in the absence of a Federal role, do you have any reason to believe that smaller states will receive the same or similar deals that manufacturers may be willing to make with larger states?

Answer. A Federal role is needed in providing increased leverage for states, particularly smaller ones, to get rebates. We cannot be sure rebates would be offered in the absence of Federal legislation. Although small states could collaborate to create the leverage that larger states have, based on informal reports, we understand that there are often hindrances to such cooperation. Federal legislation could help those states, as well as assure that manufacturers continue to have a clear incentive to offer on-going rebates.

Question No. 3. For how many services provided by the Medicare and Medicaid program does HCFA, its intermediaries, or its contractors require that a health care provider or institution obtain "prior approval" or a "second opinion?" The National Governors' Association and the American Public Welfare Association have strongly argued for the retention of prior approval programs. Would HCFA agree that for certain types of drugs or expensive drugs (like AZT or pentamidine) that prior approval should be required, regardless of whether the product is subject to a manufacturer's rebate? Please provide any additional suggestions you have for prior approval language.

Answer. With respect to the Medicaid program, HCFA does not require States to implement prior approval or second opinion procedures for any services. Rather HCFA policy permits States to impose certain limitations like prior authorization procedures. Although you noted that the National Governor's Association (NGA) and the American Public Welfare Association (APWA) have strongly argued for the retention of prior approval programs, these organizations are actively involved in representing State interests and support States in their effort to retain as much flexibility as possible in the administration of their Medicaid programs. I believe it is therefore inappropriate to cast NGA and APWA as supporting *Federally-mandated* prior approval programs when in fact the NGA's Conference requested the President's promise of no more Federal. mandates. However, it is highly likely that these organizations would support retention of *Federal policies which permit* States to develop and implement prior approval procedures.

While we do not object conceptually to States developing utilization control mechanisms like prior approval procedures for certain types of drugs or high cost drugs, we do object to requiring States to implement prior authorization requirements for Federally specified drug products, whether or not those products are subject to manufacturer rebates. In fact, we have always encouraged States to develop utilization control procedures for those items and services which it finds are prone to overutilization or abuse, or for which less costly alternatives may be available. However, any limitations developed by States are carefully scrutinized to ensure that access to quality care is not hampered, especially in the case of emergency services and to ensure that discrimination among Medicaid eligibles whether by eligibility status, diagnosis, type of illness or condition does not occur.

Thus State Medicaid agencies may use prior approval in their prescription drug programs. For example, in California approval may be obtained from a Medi-Cal consultant for covered non-formulary items or services; authorization may only be granted for the lowest cost item or service that meets the patient's medical needs.

Under current Medicare law PROs have authority to require prior authorization of hospital admissions and certain surgical procedures. As part of PROs contract requirements there are currently 10 procedures subject to prior review. Although no explicit authority in the law or regulations permits any other entity to require prior authorization, we are conducting a demonstration project required by OBRA 86 concerning prior and concurrent authorization for post-hospital extended care services and home health services furnished under Medicare.

As part of the President's FY 1991 budget submission, we have proposed to extend to carriers the authority to use prior authorization for medical services and equipment as a condition for payment to physicians who overutilize Part B services. It is our view that quality of care would be improved by the restriction of inappropriate services and equipment.

With regard to your suggestion that prior approval be required for drugs such as AZT, according to a recent survey conducted by the Intergovernmental Health Policy Project, most of the States already require prior approval for ten drugs used to treat AIDS, ARC, or HIV infection.

Question No. 4. As you know, therapeutic interchange is widely used in medical practice. In fact, it is commonly used by hospitals that receive Medicaid dollars, as well as HMOs that serve Medicaid ambulatory patients. How many Medicaid and Medicare recipients are enrolled in HMOs that use therapeutic interchange in their drug programs? How many of these HMOs use therapeutic formularies for these patients, Are you concerned in any way about the use of therapeutic formularies in these settings?

Answer. With regard to the specific data, this is provider information that HCFA would not have readily available.

Conceptually, I am less concerned about the use of such formularies in controlled settings such as in hospitals and HMOs, than I am about their use in an open system such as the State Medicaid programs.

I can share with you some information provided at the GHAA proceedings in June of this year. GHAA reported that "In keeping with cost containment strategies, many managed care health, plans are now scrutinizing the pharmacy component of their plan's health care delivery system." The Arizona system was used as an example. As you may know, the Arizona Health Care Cost Containment System (AHCCCS) is a Medicaid demonstration project that uses prepaid health plans such as HMOs and IPAs to provide health care to Medicaid recipients; each plan develops its own formulary for covered drugs. AHCCCS has developed a five-part pharmacy report format for its contracting health plans which focuses on quality of care and utilization of services. We have not had the opportunity to review the results of this approach. It is this type of information that may help to determine how therapeutic interchange is used, and one of the reasons that we want to test and evaluate such activities.

Question No. 5. Dr. Wagner from the OTA testified that in New York State, 63 percent of prescriptions for multiple source drugs were filled with originator multiple source drugs. It seems to me that we could do a much better job in promoting the dispensing of high-quality generic products in lieu of the more expensive originator multiple source products when the physician has not issued a restrictive prescription. What can HCFA do to better enforce the "brand medically necessary" provision? Does HCFA support the Federal "look behind" provision as included in S. 3029?

Answer. We are currently addressing the entire issue of multiple source drugs. Recently, HCFA and the HHS office of the Inspector General undertook a review of the State's compliance with Federal regulations limiting payments for selected multiple source drugs under the Medicaid program. Payment for such drugs in the aggregate may not exceed what those payments would have been had the HCFA upper-payment limit been actually paid for all of the States purchases of multiple source drugs which are subject to those limits. To conduct its review the OIG developed a computer program to test State's compliance. This program will be provided to States and HCFA regional offices for reviews and testing of State compliance with our present regulations. We expect the increased review and attention will result in better performance by the States in appropriately paying for multiple source drugs.

HCFA can also better enforce existing requirements for generic dispensing through increased auditing of payment limits and other rules, tightening the use of brand medically necessary language, focused review for drugs that are commonly thought to be over-prescribed or have street value. Also, we could encourage States to adopt stricter payment limits for name brand drugs when generic equivalents are available.

The specific provision you reference would require the Secretary to "look behind" the State's review of the dispensing of generic drugs. We would audit for appropriateness under State law1 and then deny FFP if the State made payments for innovator multiple-source drugs when a noninnovator multiple-source drug could have been dispensed. We support this position, although believe the Secretary should be given added flexibility.

Question No. 6. Medicaid drug sales constitute 10–13% of the average manufacturer's market. Hospitals and other institutional sales can constitute anywhere from 30 to 40%. The drug manufacturers have given the hospital and institutional market substantial discounts on their prices for many years—some as high as 70%. Is there any evidence to suggest that the large discounts given in that substantial segment of the market has impacted on drug manufacturers' R&D? How can we conclude that the manufacturers' giving discounts to a smaller segment of the market will adversely affect R&D if there is indeed no evidence to suggest that discounts in a larger segment of the market has not?

Answer. I'm not sure we can conclude anything—one way or the other. For example, there is no way to determine whether a discount program would force pharmaceutical manufacturers to cut costs in their R&D components as opposed to other components. Clearly, the pure numbers—target savings of about $300 million when the industry spends close to $8 billion on R&D would not seem to be overly disruptive. However, discounts vary tremendously by product and manufacturer and type of purchaser. PPOs and other open systems receive some discounts or rebates from manufacturers, but rarely above 25%. Like PPOs, Medicaid is an open system.

Our primary goal is to assure access and to make Medicaid more affordable for our country both at the Federal and State level. We believe that in our attempt to achieve access to quality drugs for our beneficiaries, Medicaid, as the largest single buyer of prescription drugs is currently paying more than is deserved for outpatient drugs. Other provider types and beneficiaries of other government programs are receiving cost reductions for their drug programs that significantly exceed those available to the Medicaid program.

Question No. 7. The Prescription Drug Payment Review Commission could have served as an excellent resource of information for the discussions and debates surrounding this issue. Do you agree that the establishment of such a Commission, as included in S. 3029, could provide significant assistance to HCFA in monitoring the success of any rebate program, and the financial solvency of the Medicaid drug program?

Answer. The Prescription Drug Policy Review Commission described in S. 3029 seems to unnecessarily complicate the issue. We believe that the Medicaid program currently contains coverage guidelines with sufficient flexibility for States to tailor prescription drug programs to their own needs aid at the same time protect the sanctity of the physician/patient relationship. The type of advisory/oversight function your bill proposes should most appropriately be the responsibility of the General Accounting Office which currently provides the function under their charter.

We do believe some additional mechanism may be needed to induce drug manufacturers to offer their products to State Medicaid programs at a reasonable price. This is purely a matter of negotiation and we have already seen evidence of a willingness to do so from certain drug manufacturers in response to pressures of Congressional action in this area.

May 27, 1986

ROBERT B. HELMS, PH. D.,
Acting Assistant Secretary, Planning & Evaluation,
Department of Health & Human Services,
200 Independence Avenue, S. W.,
Washington, DC. 20201

Dear Dr. Helms: We are writing to express the views of our organizations on reforming Medicaid payment for prescription drugs. Some of us have already commented individually on specific government proposals (i.e., the Pharmacist Incentive Program—PhIP—and the Competitive Incentive Program—CIP). Since then we have concluded that there are broad principles that must be reflected in any acceptable reform measure. These principles are set forth in the attached paper.

Briefly, we believe that reform of the Medicaid drug program should reduce needless government regulation, improve administrative practices, and rely on competitive forces in the marketplace to achieve savings. These broad principles have two specific implications for Medicaid drug program reform. First, all prescription drug products should be reimbursed at prices determined in the competitive marketplace. Second, a voucher system should be employed to reduce claims processing costs. Our reasons for holding these views are provided in the attached paper.

We understand that a Notice of Proposed Rule Making on Medicaid drug program reform is under consideration. We are writing now so that these principles, which are supported by all components of the nation's drug distribution system, can be considered in your planning.

Sincerely,

ROBERT J. BOLGER, *President, National Association of Chain Drug Stores*

GERALD J. MOSSINGHOFF, *President, Pharmaceutical Manufacturers Association*

JOSEPH A. ODDIS, *Executive Vice President, American Society of Hospital Pharmacists*

JOHN F. SCHLEGEL, *President, American Pharmaceutical Association*

CHARLES S. TREFREY, *Executive Vice President, National Wholesale Druggists' Association*

R. TIM WEBSTER, *Executive Director, American Society of Consultant Pharmacists*

CHARLES M. WEST, *Executive Vice President, National Association of Retail Druggists*

Enclosure.

PRINCIPLES FOR REFORM OF MEDICAID PAYMENT FOR OUTPATIENT DRUGS

INTRODUCTION

Following the implementation of the Medicaid program in 1965, pharmacists, more than other provider groups, enthusiastically supported and participated in this important health care program for the needy. Ten years later, in 1975, the Federal government adopted the Maximum Allowable Cost/Estimated Acquisition Cost program. This controversial approach established a complex set of formulas that imposed artificial controls on the retail marketplace and interfered with professional judgments regarding the selection of prescription drug products provided to the poor. In more recent years, the Medicaid program has been moving toward a reimbursement scheme that would further reduce reimbursement to pharmacies.

The Federal Government seems content to capture limited, short-run savings at the expense of retail pharmacy providers and the research-intensive pharmaceutical manufacturing industry, while ignoring significant opportunities for reducing health care costs by allowing the competitive marketplace to function efficiently and effectively. In response, many prominent national organizations representing all components of the nation's drug distribution system—pharmaceutical manufacturers, drug wholesalers, independent pharmacies, chain drug stores, hospitals and the pharmacy profession—have been advocating a complete overhaul of the Medicaid drug reimbursement system. These organizations are calling for less government intrusion, so that the nation's pharmacies can continue to provide the highest standard of care and service to needy people.

FUNDAMENTAL PRINCIPLES

Reduce needless Federal regulation. American society experienced a virtual explosion in Federal Government regulation during the past decades. Between 1970 and 1979 the number of pages published annually in the Federal Register nearly tripled and the number of pages in the Code of Federal Regulations increased by over two-thirds. The current Medicaid drug program was part of this growth.

Although well-intended when originally developed, the Medicaid drug program has failed to keep pace with rapid changes in health care delivery over the past ten years. This has resulted in pharmacy providers subsidizing the Medicaid program because they frequently lose money when they fill a Medicaid prescription. Moreover, the hardship and uncertainty imposed on business by this over-regulation has impeded business decisions and expansion plans, ultimately reducing economic growth and the creation of jobs in the private sector. This over-regulation is particularly burdensome to small and independent businessmen and women, such as pharmacists who are proprietors of community pharmacies, and causes them to defer or terminate plans for expansion.

Our position on Medicaid drug reimbursement is directed at minimizing governmental intrusion by reforming or eliminating regulations which are unnecessary and counterproductive.

Improve administrative practices. Approximately 171 million claims are processed each year by the Medicaid program. Wasteful administrative overhead consumes resources that should be targeted on the health care needs of beneficiaries. Furthermore, current inefficient administrative practices impose needless hardship on retail pharmacies due to slow and erratic payment, and excessive paperwork. Initiatives to improve administrative practices can reduce both public and private costs to process Medicaid claims, and insure timely payment to pharmacies.

Rely on the marketplace. We do not need excessive Federal regulation to solve the problems of Medicaid drug Costs. As long as we let the forces of the marketplace work without undue interference, the ingenuity of consumers, businesses, producers and inventors will do that for us. The retail drug market is dominated by self-pay customers who, along with increasingly cost-conscious third party payers, impose competitive discipline on marketplace prices. If we allow it to, the magic of the market-place will unleash new competition, giving the Medicaid program lower prices, and Medicaid beneficiaries more choices and better services.

IMPLICATIONS FOR THE MEDICAID DRUG PROGRAM

To achieve meaningful reform, public policies governing the Medicaid drug program should be revised along the following lines:

- Base drug reimbursement on sound economic principles through the elimination of artificial controls. This would be achieved by replacing the current provisions governing reimbursement with marketplace pricing, i.e., usual and customary charges for all products and services, capped, for example, at the 90th percentile for all charges within a state.
- Implement a new and streamlined reimbursement mechanism that would greatly lower administrative expenses in the program. Such a worthwhile objective can be easily accomplished by coupling marketplace pricing with an innovative system of drug vouchers.

States shall build upon this basic set of principles established by the Federal Government, tailoring their individual programs to fit local circumstances.

COMMUNICATIONS

STATEMENT OF THE ALLIANCE FOR AGING RESEARCH

Mr. Chairman and members of this Committee, the Alliance for Aging Research is pleased to be able to provide testimony on the issue of cost reimbursement for the Medicaid program. Since more than 3 million older Americans participate in the Medicaid program—representing approximately 15 percent of all Medicaid recipients—this issue is of great concern to our organization.

I would like to commend you Mr. Chairman for moving this debate on such an important policy issue into an open and public forum and out of the closed process of the budget summit. Indeed, the development of a proposal on the part of the Office of Management and Budget for the therapeutic substitution of prescription drugs to Medicaid patients has raised the concern of many national organizations that promote health, civil rights, economic justice and other public interest concerns. The Alliance for Aging Research was one of the first of 15 national bodies its join a coalition in opposition to the OMB proposal because of the serious and adverse impact on equal access to quality health care if enacted.

The Alliance recognizes the need to conserve public funds in the Medicaid program and the nation's entire health care budget. We, would like to commend in particular Senate Special Committee on Aging Chairman David Pryor for bringing this and other important health care issues to the national agenda.

Since the OMB proposal was submitted last June, several legislative as well as industry proposals have been put on the table. To help guide this Committee and others, the Alliance has developed three basic principles which any final proposal should embrace. Any proposal that becomes law, we believe: (1) should provide equal access to the latest medical and pharmaceutical advances available; (2) should not subject the poor, the elderly or any other group to any form of therapeutic substitution; and, (3) should encourage continued research into new and improved pharmaceutical products. This last point is especially critical due to the rapidly increasing numbers of older people in our society. Research and discovery must to accelerated precisely in those age-related illnesses and disabilities that occur with increasing frequency among the old.

EQUAL ACCESS

Inherent in any drug reimbursement system based on a restricted or closed formulary is the possibility that some drugs will not be allowed into the system. To create a national formulary, as proposed in both the OMB proposal and S. 2605, would be a step away from equal access to the latest medical and pharmaceutical advances. Due to the fact that it takes time to review a drug, a restrictive formulary often keeps newer drugs out of the hands of the neediest patients.

To appreciate how a formulary can keep new and helpful drugs out of the hands of the poor, one only needs to look at states that have restrictive formularies in place. The largest state Medicaid program, California's Medi-Cal, currently does not include three new breakthrough drugs—listed as "1-A Drugs" by the Food and Drug Administration—under their formulary system. After experimenting with restrictive formularies some states, most recently Louisiana and Oklahoma, have moved to abolish them.

We would also urge the Committee to take great care in developing any proposal dealing with the prior approval process as part of a drug rebate or reimbursement system. A restrictive form of prior approval or one left up to state option and guidelines could have, the same adverse reaction on access to new medicines as a restrictive formulary system.

In March of this year, the Pepper Commission report on Access to Health Care and Long-Term Care for All Americans called for increasing access by eliminating the distinctions of a two-class medical system which distinguishes between the poor and other Americans. It is an objective the Committee should keep in mind when developing a final proposal.

NO THERAPEUTIC SUBSTITUTION

The Alliance for Aging Research strongly opposes the adoption of any form of therapeutic substitution as an inherently dangerous and flawed concept. In stating our opposition to therapeutic substitution we join many medical and private voluntary health organizations including the American Medical Association, the Alzheimer's Association, the Arthritis Foundation, the American Heart Association, the Parkinson's Foundation and others concerned about the health of older Americans.

Therapeutic substitution is based on the faulty notion that drugs within the same therapeutic class but with different chemical formulas will achieve the same result when prescribed to different patients. Many older people take several different prescription medicines every day. Therapeutic substitution does not adequately address the wide variety of biological responses that are observed in a geriatric patient population. Also ignored is the complex pharmacodynamics of drug absorption, distribution and elimination that are hallmarks of an older patient. Patients afflicted with certain age-related illnesses, including Parkinson's disease, are especially vulnerable to adverse and possible deadly reaction to unwise therapeutic substitution.

Of the pending proposals, the OMB plan to mandate the cheapest drug to poor patients includes the purest form of therapeutic substitution. The Alliance expresses its concern that the administration offered this critical health policy proposal without approval or discussion within the Department of Health and Human Services.

We are pleased that the most recent legislative proposals in both the Senate and the House of Representatives have moved away front therapeutic substitution.

CONTINUED RESEARCH

As an organization devoted to increasing both private and government support for research in human aging, we stress the need to develop a proposal which allows and encourages American companies to continue research and development in new medicines and health care products. We believe proposals which would limit access to new medicines in Federal health programs, currently the largest reimburser of pharmaceuticals, would decrease industry incentive for research.

The pharmaceutical industry's commitment to research is tremendous. This year, for the third year in a row, R&D spending by private, research-based pharmaceutical companies will surpass spending by the entire National Institutes of Health. Of the more than $8 billion invested in R&D by private companies, approximately half is spent on the development of new medicines for older people. As a proportion of research spending devoted to aging, this is far greater than the current level of aging research conducted at the NIH.

Increasingly, private companies are becoming involved in both basic and clinical research in the chronic disabilities that rob the quality of life from later years. We are beginning to see the results of that investment in new discoveries to reduce frailty in the elderly, bone loss and osteoporosis, breakthrough research in the genetic basis of osteoarthritis, and new approaches to Alzheimer's disease. We need to keep this spirit of discovery alive.

Statement of Allen's Family Practice Clinic of Ponchatoula

Mr. Chairman, I appreciate very much the opportunity to express my reservations about legislation before this committee that would impose restricted drug formularies on state Medicaid programs. We had a restricted formulary in Louisiana for 12 months in 1988 and 1989 and the results were so bad the state legislature opened it up again. The last thing we need is the Federal government forcing us to close it once more.

I am a family physician in a small town in Louisiana, and I have a degree in pharmacy as well. For the past several years, I have been a member of the state formulary committee, appointed by the Louisiana State Medical Society as their representative, and an adviser to Louisiana's Department of Health and Hospitals. So I could see what was coming when the legislature decided to put Louisiana on a restricted, closed formulary in September 1988.

As a practicing physician, I found I could no longer prescribe proper medications for my patients when medications on the state formulary were ineffective. I a person required a hypertensive medication, and what was on the formulary didn't work, the patient just couldn't get the right medication. I'd write the prescription and the pharmacy wouldn't fill it, so the patient would end up throwing the prescription away.

I'll give you an example of what can happen with restricted formularies. I have a 60-year-old Medicaid patient, Zell Farrage, who suffers from arthritis. Last summer Mrs. Farrage had an extreme case of osteo-arthritis in her left knee and had to undergo a knee-replacement operation. Immediately after the operation, she developed a staph infection in her kneecap. The only antibiotic which could be used against the infection outside of the hospital was Cipro, one of the new quinolone antibiotics which—like almost all drugs still on patent—was excluded from the Louisiana formulary. Mrs. Farrage could not afford to pay for the prescription, which would have cost approximately $250, so she was re-hospitalized in order to receive proper care. She stayed in the hospital for 10 days and received intravenous antibiotics, which *were* covered by Medicaid. The hospitalization cost about $600 a day. But when she left the hospital, Mrs. Ferrage still needed a massive application of antibiotics. So I contacted Cipro's manufacturer, Miles Pharmaceutical, and received enough samples of the antibiotic to last her 20 days. After that, she recovered from her infection—no thanks to the Medicaid program.

This is what doctors have to do when they are faced with closed formularies. We beg and borrow for our indigent patients. We give them samples so they can get immediate medication without having to pay for it themselves.

That is why 8 out of the 11 members of the state formulary committee formed a coalition that we named Helpful Medicine for Louisiana. We agreed something had to be done to improve the quality of medications available under Medicaid. The coalition included the Louisiana Diabetic Association, Leukemic Association, Rheumatology Society, Pediatric Society and Academy of Family Physicians. It also included the AFL-CIO and the NAACP. We didn't have any money, but we worked hard to bring the message to the public, to politicians and to the newspapers. We had a six-city blitz throughout the state during one 48-hour period, with phone calls, letter writing and personal contact. We appeared on radio and TV.

In September 1989, the legislators reversed themselves and opened up the formulary. They all admitted they made a mistake, but meanwhile there was a terrific amount of pain and suffering. Finally, however, we have a formulary that we can live with. It only restricts cough-and-cold medications and cosmetics. We actually don't like any restrictions, but we can usually get around them if we have to.

Now we have to worry that the Federal Government will impose severely restricted formularies on us again. S. 2605 would repeal Louisiana law on access to Medicaid drugs. It would do away with our open Medicaid formulary. OMB's proposal is even worse, since doctors would not even be told their patients were getting a different medication from the one prescribed. I cannot understand the logic of these proposals.

Mr. Chairman, we have over 600,000 people on Medicaid in Louisiana. Over 50 percent of them are children less than 19 years old. If society really wants these children to grow up to be healthy adults, to become healthy citizens and healthy workers, they have to be given the right medicines when they get sick.

Nobody wants to be sick. Nobody wants to be poor. But when you're both poor and sick, it's much worse when you have no money to buy the medications you need. And it's terrible when the only thing that's offered to you by Medicaid is inferior substitutes. Please don't impose that on Louisiana. Or on any other state.

Thank you.

STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

The American College of Cardiology (ACC) appreciates the opportunity to submit testimony to the Senate Finance Committee Subcommittee on Health for Families and the Uninsured concerning proposals to modify the Medicaid drug reimbursement program. We commend Chairman Riegle for holding public hearings on this matter and understand the importance of efforts to obtain better prices for the Medicaid drug program; however, we cannot support attempts to use therapeutic substitution as a cost savings measure.

The ACC represents 18,000 cardiovascular specialists dedicated to fostering optimal care and cardiovascular disease prevention through continuing education and the development of practice guidelines.

Medical advances and public education efforts have combined to make significant strides in the battle against cardiovascular diseases, including heart attack and stroke. Despite this progress, cardiovascular disease remains America's number one killer in the United States and worldwide. More than one in four Americans suffer some form of cardiovascular disease at an estimated cost in 1990 of $94.5 billion in medical expenses and lost productivity. About 61 million Americans suffer from high blood pressure (hypertension), the most prevalent cardiovascular disease, a heart attack risk factor, and a leading stroke contributor. The elderly and black are more prone to hypertension. Because Black Americans tend to be less economically advantaged, the cost of these drugs is an important issue, since drugs are critical in treating hypertension, heart failure, and chronic coronary artery disease.

The ACC applauds Senator Pryor's efforts in S. 2605, the Prescription Pharmaceutical Access and Prudent Purchasing Act, to reduce the costs of prescriptions for Medicaid patients and all citizens. However, the bill contains provisions for therapeutic substitution which the ACC has opposed since inception of the concept.

Our opposition to therapeutic substitution should not be construed to represent opposition to generic substitution, the act of dispensing a different brand or unbranded drug product which is the same chemical entity and bioequivalent to the drug product prescribed.

However, the ACC vigorously opposes efforts, by both Congress and the Office of Management and Budget, to permit pharmacists to dispense prescription drugs to patients without the specific prescription of a physician. Recent actions to permit so-called "therapeutic substitution" by pharmacists, (i. e., the practice of dispensing an alternate chemical entity from the same therapeutic class for the drug product prescribed by a physician, e.g., procainamide for quinidine) represent a real and present danger to individual patients.

We commend Senator Pryor's modification of the therapeutic substitution provision contained in the earlier draft legislation; however, the ACC continues to have reservations about the modified approach to therapeutic substitution, now called "therapeutic alternative." S. 2605 contains a provision which would require the pharmacist to consult the prescribing physician before filling a prescription for a drug which has a "therapeutic alternative."

Under S. 2605, if the physician cannot be reached for consultation while the patient is waiting in the pharmacy, the patient would be given a three day supply of the prescribed medication and told to return for the full prescription at some time within the next three days. The changes in the bill reduce the dangers to patients but may increase the inconvenience and cost (in time spent) by pharmacists, physicians, and patients.

Therapeutic substitution is a flawed concept and dangerous practice. Medical literature is replete with examples illustrating undiscovered or unanticipated differences between patients or drugs that will, lead to an unpredicted response when another drug is substituted. The database documenting differences between patients' response to drugs is overwhelming and growing.

In the strongest possible context, we believe that therapeutic substitution runs counter to therapeutic principles learned by physicians and medical students. Medical education emphasizes individualized therapy based on knowledge of patients and the differences that exist between all drugs. The value of teaching rational therapeutics cannot be counterbalanced by the potential for reduced cost of medications. Therapeutic substitution mistakenly assumes that most patients and drugs can be reliably categorized so that pharmacists can change therapy without risk of harm to the patient.

The evaluation of the health needs of a patient involves integration of full knowledge of the individual patient's medical history, physical status, and the disease process. This is the province and the responsibility of the physician who has been trained to collect and integrate such data. The choice of specific drug therapy and the necessary evaluation of a patient's response to that treatment must also be the province and the responsibility of the physician.

For each patient, a specific drug or combination of drugs has been or should be prescribed for a specific problem by the patient's physician. Since the pharmacist does not have available complete clinical information for specific patients and does not possess the medical training on which base a therapeutic decision, "therapeutic substitution" may result in the patient receiving a drug agent which may lack efficacy, which produces life-threatening toxicity or which interacts adversely with other drugs the patient is receiving. Each of these possibilities is an unacceptable consequence and should not be permitted.

The American College of Cardiology looks forward to working with Congress in maintaining the availability of medication for Medicaid patients and all citizens while providing quality patient care without unnecessary risk to the patient's health and well-being.

Thank you for your careful consideration of our views.

STATEMENT OF THE AMERICAN COLLEGE OF RHEUMATOLOGY

The American College of Rheumatology (ACR) is the only professional organization of physicians and scientists devoted to the study, treatment, and care of people with rheumatic diseases. We are pleased to submit this statement to the Senate Finance Subcommittee on Health for Families and the Uninsured on therapeutic substitution as you continue your deliberations on Medicaid prescription drug pricing.

Therapeutic substitution by pharmacists refers to the practice of dispensing an alternate chemical entity from the same therapeutic class for the drug prescribed by a physician. Therapeutic substitution is different from generic substitution in that generic substitution refers to the prescribing of a drug by a physician leaving the choice of brand to the dispensing pharmacist. The same chemical entity in the same dosage form is dispensed by the pharmacist. Therapeutic substitution is a pharmacist-initiated act by which a pharmaceutical or therapeutic alternate for the physician-prescribed drug is dispensed without consulting the physician, e.g. ibuprofen for naproxen.

The extent of therapeutic substitution is unknown and depends on how and by whom it is defined. Some HMOs and third-party payors have advocated therapeutic substitution as a way to control pharmacy costs. And while some require pharmacists to consult a patient's physician before substituting a different drug for the one prescribed, many do not. Although Washington state is currently the only state where therapeutic substitution is permitted by law at the local pharmacy level, almost one-third of HMO pharmacy plans now allow the practice, according to a University of Florida study.

In some states, legislation, regulations or state licensing practices permit therapeutic substitution, giving pharmacists varying degrees of dispensing authority. In addition, there are efforts underway to promote legislation that would allow therapeutic substitution to be practiced in community pharmacies and managed care organizations across the country.

The evaluation of the health needs of any individual involves integration of full knowledge of the person's family and medical history, physical status, and the disease process; and is the responsibility of the physician who has been trained to collect and integrate such information. It follows, therefore, that the choice of a specific drug therapy, and the necessary evaluation of an individual's response to that treatment, must also be within the purview and the responsibility of that physician.

For each patient, a specific drug or combination of drugs has been or should be prescribed for a specific problem by the patient's physician. Since the pharmacist does not have available complete clinical information for individual patients, "therapeutic substitution" may result in the patient receiving a drug which may have previously been tried unsuccessfully; one which may lack efficacy in the current stage of an illness; one which may be prescribed in an inadequate or excessive dosage; or one which interacts adversely with other drugs the patient is receiving. Each of these possibilities is an unacceptable consequence and should not be permitted. Furthermore, factors such as the safety of therapeutic substitution have not been demonstrated.

One of the most important aspects of the care rheumatologists give patients is the ability to choose the pharmacological agents necessary for the management of their diseases. in order to treat patients effectively, rheumatologist commonly rely on a wide variety of medications. Such medications include aspirin and a large group of nonsteroidal anti-inflammatory drugs (NSAIDs) which include common over-the-counter drugs, such as ibuprofen, and prescription drugs, such a piroxicam and sulindac. In addition, other categories of medications, such as glucocorticoids, gold salts, and immunosuppressive agents, are important components of a comprehensive treatment program when used alone or in combination with NSAIDs.

Within a particular class of medications, there are often many drugs available to physicians for their patients. In one patient, only one of those medications may be tolerated and be of benefit, while another patient may only tolerate and benefit from another of the drugs available. With the well-recognized individual variability in response to these medications, there is no way of knowing other than through a systematic approach to each person's particular circumstances, *choosing appropriately from among the various drugs available,* which drug(s) is (are) of benefit to an individual patient, or which will not have deleterious side effects. Pharmacists do not have sufficient information upon which to make those decisions.

POSITION

1. The American College of Rheumatology opposes, in the strongest terms, legislation or regulation that would permit prescription therapeutic substitution by pharmacists as an action which is not consistent with quality patient care and which will pose unnecessary risks to patients' well-being.

2. Generic substitution may be appropriate when, in the judgement of the physician, different brands of the same drug will provide equivalent efficacy and safety.

STATEMENT OF THE AMERICAN HEART ASSOCIATION

The American Heart Association, AHA, appreciates the opportunity to submit the following statement to the Senate Finance Subcommittee's hearing record on proposals to modify the Medicaid drug reimbursement program. We commend Chairman Riegle for holding this hearing.

To effectively develop policy and monitor cardiovascular drug-related issues in Congress, at the Food and Drug Administration, and at the National Heart, Lung, and Blood Institute, the AHA and the American College of Cardiology established the ACC/AHA Cardiovascular Drugs Committee. While the ACC plans to submit a separate statement to the Subcommittee, both the ACC and the AHA, acting as individual organizations and as the Cardiovascular Drugs Committee, vigorously oppose efforts to permit pharmacists to dispense prescription drugs to patients without the specific prescription of a physician.

The AHA and its over 2.7 million volunteers are dedicated to the reduction of disability and death from cardiovascular diseases and stroke. The programs of the AHA have made significant strides in the battle against cardiovascular diseases, including heart attack and stroke. Despite advances, cardiovascular diseases remain the number one killer in the United States and worldwide. More than one in four Americans suffer some form of these diseases at an estimated cost in 1990 of $94.5 billion in medical expenses and lost productivity.

Drugs are critical in treating hypertension, heart failure, and chronic coronary artery disease. About 61 million Americans suffer from high blood pressure (hypertension), the most prevalent cardiovascular disease, a heart attack risk factor, and a leading stroke contributor. The elderly and blacks are more prone to hypertension. Because Black Americans tend to be poorer and less economically advantaged, lower priced drugs must be made available to them.

The AHA applauds Senator Pryor's intention in S. 2605, the Prescription Pharmaceutical Access and Prudent Purchasing Act, to reduce the costs of prescriptions for Medicaid patients and all citizens. However, the bill contains provisions for therapeutic substitution which the AHA has opposed since inception of the concept.

Our opposition to therapeutic substitution should not be construed to represent objection to generic substitution, the act of dispensing a different brand or unbranded drug product which is the same chemical entity and bioequivalent to the drug product prescribed.

However, the AHA vigorously opposes efforts to permit pharmacists to dispense prescription drugs to patients without the specific prescription of a physician. The AHA is also on record in opposition to the Office of Management and Budget's plan to save Medicaid resources through the practice of therapeutic substitution. Recent actions by some states to permit so-called "therapeutic substitution" by pharmacists (i.e., the practice of dispensing an alternate chemical entity from the same therapeutic class for the drug product prescribed by a physician) represents' a real and present danger to individual patients.

The evaluation of the health needs of a patient involves integration of full knowledge of the individual's medical history, physical status, and the disease process. This is the province and the responsibility of the physician who has been trained to collect and integrate such data. The choice of specific drug therapy and the necessary evaluation of a patient's response to that treatment must also be the province and the responsibility of the physician.

For each patient, a specific drug or combination of drugs has been or should be prescribed for a specific problem by the patient's physician. Because the pharmacist does not have available complete clinical information for specific patients and does not possess the medical training to base a therapeutic decision, "therapeutic substitution" may result in the patient receiving a drug agent which may lack efficacy, which produces life-threatening toxicity or which interacts adversely with other drugs the patient is receiving. Each of these possibilities is an unacceptable consequence and should not be permitted.

The AHA commends Senator Pryor's modification of the therapeutic substitution provision contained in the earlier draft legislation; however, we continue to have reservations about the modified approach to therapeutic substitution, i.e. "therapeutic alternative." S. 2605 contains a provision which would require the pharmacist to consult the prescribing physician before filling a prescription for a drug which has a "therapeutic alternative."

The AHA strongly opposes the establishment of a list of "therapeutically alternative equivalent drugs" because there are very few or no such drugs. A qualified panel of physician specialists working as a formulary committee, the National Pharmacy and Therapeutics Committee, as proposed under S. 2605, will be hard pressed to construct a list of more than two or three drugs which could be safely substituted even after consulting the patient's physician. Such a small list would mean that safe and effective implementation of therapeutic substitution in any form would not be cost effective.

Despite modification of the therapeutic substitution provision from the draft legislation, the principles of therapeutic substitution remain in S. 2605, Prescription Pharmaceutical Access and Prudent Purchasing Act of 1990. In S. 2605, therapeutic substitution occurs only after consultation. However, S. 2605 assumes that physicians will always have the information necessary to know when substitution could be dangerous or inappropriate.

Under S. 2605, if the physician cannot be reached for consultation while the patient is waiting in the pharmacy, the patient would be given a three day supply of the prescribed medication and told to return for the full prescription at some time within the next three days. The changes in the bill reduce the dangers to patients but dramatically increase the inconvenience and cost (in time spent) by pharmacists, physicians, and patients.

In addition to the modified therapeutic substitution provision, S. 2605 contains a proposed bidding program and a formulary for prescription drugs. Any cost savings from the possible use of a bidding program and a formulary would be lost by the additional time spent by pharmacists and physicians trying to contact each other to discuss changing the patient's medications.

Therapeutic substitution is a flawed concept and dangerous practice, even if physicians can override the substitution mandate. Medical literature is replete with examples illustrating undiscovered or unanticipated differences between patients or drugs that will lead to an unpredicted response when another drug is substituted. The database documenting differences between patients' response to drugs is overwhelming and growing. It is incorrect and dangerous to assume that one can predict all of the instances in which changing from one drug to another will be safe.

Providing indemnity to pharmacists will not help patients who suffer needlessly from being denied medication carefully and thoughtfully selected by their physician. Indemnity does not cancel the costs of clinical reassessment, retitration of therapy or treating therapeutic misadventures, including adverse reactions.

Therapeutic substitution runs counter to therapeutic principles learned by physicians and medical students. Medical schools emphasize individualized therapy based on knowledge of patients and the differences that exist between all drugs. The value of teaching rational therapeutics cannot be counterbalanced by the potential for reduced cost of medications. Therapeutic substitution mistakenly assumes that most patients respond similarly to different drugs and that patients and drugs can be reliably categorized so that pharmacists can change therapy without risk of harm to the patient.

The American Heart Association looks forward to our continued dialogue with Senator Pryor and his staff in reducing the cost of medication for Medicaid patients and all citizens while providing quality patient care without unnecessary risk to the patient's health and well-being.

Thank you for your careful consideration of our views.

Statement of the American Psychiatric Association

The American Psychiatric Association, a medical speciality society representing more than 36,000 psychiatrists nationwide, appreciates the opportunity to submit this statement on Medicaid reimbursement for prescription drugs.

The APA acknowledges the rapid growth in Medicaid expenditures on prescription drugs, but will confine our comments for this hearing to one aspect of current Medicaid drug proposals: therapeutic substitution.

The Medicaid prescription drug program is an optional benefit for which a Federal match is made. Although the drug program is not a "basic medical service," all

50 states provide some type of outpatient prescription drug benefit in addition to covering drugs prescribed incidental to hospitalization of a Medicaid patient.

The Congress may consider a proposal which would require some sort of therapeutic substitution of prescription drugs. This is currently embodied in a proposal developed by the Office of Management and Budget as part of the ongoing budget deficit "summit" negotiations between the white House and the Congress.

Under the Office of Management and Budget proposal, the Secretary of Health and Human Services would be required to designate one or more drug formularies to be used by state Medicaid programs to determine therapeutic substitution. A single national formulary would be established by 1992. States would be required to negotiate the "best price" for one or more drugs in each therapeutic class. These drugs would become the "preferred drug" for purposes of Medicaid reimbursement.

Once the preferred drug was established, pharmacists would be required to substitute the preferred drug for a named non-preferred drug unless the physician had specified on the prescription form, and in a method approved by the Secretary, that the prescribed non-preferred drug was "medically necessary.

The APA is deeply concerned that therapeutic substitution proposals—however carefully constructed—would jeopardize the quality of health care for an already vulnerable group of Americans. while we recognize concern in some quarters about the rapid growth in Federal and state expenditures on prescription drugs under the Medicaid program, we believe that therapeutic substitution is not an acceptable cost containment alternative.

The OMB proposal is particularly troubling. In addition to requiring the implementation of a national formulary, the proposal would also *require* pharmacists to substitute the "preferred" drug except where the physician had clearly specified (in a form specifically approved by the Secretary) that the non-preferred drug was to be used. Such mandatory substitution would take place without the knowledge of the physician or patient.

It is important to appreciate the legislative "spin-control" inherent in use of the word "preferred. " Let us be clear and understand that the "preferred" drug is not necessarily therapeutically preferred but *economically* preferred. It is not what the patient and his or her physician prefer based upon medical need but rather what is in the payor's economic interest. As a matter of prudent medical management, we believe that an automatic substitution without notification to the physician is a direct and economically-driven interference in the practice of medicine by psychiatrists or any other physician. This automatic substitution of one drug for another may potentially reduce Medicaid outlays, but it also runs the risk of causing severe harm to the patient.

For example, a patient presenting with depression would be a candidate for any of the tricyclic antidepressants, such as imipramine, elavil, norpramin or desyrel. While any of these drugs within the so called "class of drugs" concept could be prescribed for the management of depression, each of the drugs has specific side effects which could contraindicate its prescription for a specific patient.

As an example, some tricyclics have a high degree of cardiotoxicity. It could be catastrophic for a therapeutic substitution of a potentially cardiotoxic drug for a drug such as desyrel which had been specifically prescribed for an older patient suffering from heart arrhythmia precisely because desyrel had a low degree of cardiotoxic effects. But it is highly plausible that such a "therapeutic substitution" could take place under the regime proposed by OMB, and the patient and the prescribing physician would be none the wiser.

The APA also is troubled by the OMB proposal's grant of outright immunity to pharmacists for liability under all state and Federal laws for any damages arising from a substitution made in accordance with the national formulary. No such protection would be granted to the prescribing physician, whose instructions could be changed without notification. As such, the proposal exposes Medicaid patients to considerable risk, accords them second-class health care status while at the same time providing immunity to the very people—pharmacists—who are entrusted with the responsibility for the therapeutic substitution. This system cannot help but promote economic rather than clinical considerations.

The OMB proposal should be deemed unacceptable to the Congress and rejected if it is put forward as part of the budget summit agreement.

Mr. Chairman, the APA does understand the concern of the Congress and the white House about increased Federal and state outlays for prescription drugs under the Medicaid program. However, proposals which—at their core—would place significant emphasis on economic incentives to use one drug over another have the potential for serious health consequences to patients, and, in the instance of the OMB proposal, would not even give the prescribing physician the opportunity to intervene on behalf of his or her patient.

The APA urges members of your Subcommittee and of the full Finance Committee to carefully consider the problems posed by therapeutic substitution proposals, and hopes you will act to ensure that the best interests of economically vulnerable Medicaid patients are not sacrificed on the altar of deficit reduction.

Statement of the American Society of Hospital Pharmacists

Mr. Chairman and Distinguished Members of the Committee: The American Society of Hospital Pharmacists (ASHP) is pleased to present its views on the three legislative proposals designed to control the costs of outpatient drugs to the Medicaid Program: S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990; S. 3029, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Act of 1990; and H.R. 5589, the Medicaid Prescription Drug Fair Access and Pricing Act of 1990. ASHP is the national professional organization of pharmacists practicing in organized health care environments such as managed care settings, skilled nursing facilities, home care providers and, of course, hospitals; membership in ASHP exceeds 23,000. ASHP has worked closely with members and their staffs and the Executive Branch on a number of issues associated with these bills, notably formulary systems and pharmacy and therapeutics committees, drug utilization review, group purchasing programs, therapeutic interchange and clinical pharmacy services.

Our members have considerable interest and expertise in the issues before you today. As concerned private citizens our members applaud the objective of these bills and their sponsors: to reduce Federal expenditures by ensuring that the Medicaid program is as efficient as possible in funding outpatient drug benefits, and also provide the best possible care to beneficiaries of Title 19. The environments in which our members practice have experienced continuous reductions in Medicaid, Medicare, and other third party payments while having to deal with budget-busting yet essential new, innovative and "high-tech" drugs; they have considerable experience in the problem of controlling drug costs.

We are, as we have been for sometime, very concerned that these legislative proposals are not the appropriate means to achieve their stated goals. Our concerns about these bills stem from our members' professional expertise and experience, not from personal economic interest. Hospital and managed care pharmacists are virtually all salaried employees, and do not gain or lose from higher or lower drug costs. Our members are responsible for the operation of formulary systems and pharmacy and therapeutics committees, purchasing activities and clinical services such as drug utilization review, patient education and counseling, and therapeutic interchange principles fundamentally interwoven into all three bills. Our members are intimately familiar with the benefits, pitfalls, and problems of these initiatives.

Our concerns about these bills focus on a number of issues:

—We believe that these bills will not result in any real savings because the gains made under Medicaid will be shifted to Medicare and private pay patients; net Federal budget gains will be, at best, nominal. We believe that these bills should seek a comprehensive solution to control the cost of drugs to providers in all federally funded programs.

—We do not believe that the concept of formulary systems and pharmacy and therapeutic committees can be translated into a national program as contemplated by S. 2605.

—We believe that these bills will have a deleterious effect on formulary systems and purchasing activities in organized health care settings, concepts that have clearly demonstrated efficiencies and are marks of high quality care which should be fostered, not weakened.

—We believe that several of the provisions in the bills are punitive and not feasible to implement.

OVERALL ECONOMIC IMPACT OF THESE PROGRAMS

Each of these legislative proposals is founded on the unstated assumption that the pharmaceutical industry will simply absorb a reduction of income, estimated by the Congressional Budget office to be $300 million per year, as a result of Medicaid rebate programs; we believe that assumption to be unrealistic. The pharmaceutical industry will need to maintain its income levels, whether for research, marketing and promotion, or maintenance of shareholder value, and reductions in income arising from Medicaid rebates will be recovered from segments of the marketplace unaffected by such programs. Even assuming that such structural shifting of costs to other market segments is an acceptable outcome, the substantial price increases to private pay patients and to Medicare should be accounted for in assessing the net benefits of each proposal. The Federal balance sheet should consider both debits and credits in assessing the real impact on these programs.

A study conducted for ASHP by the Sonderegger Research Center at the University of Wisconsin entitled "The Pharmaceutical Access and Prudent Purchasing Act of 1990: Estimating the Impact on Institutional Pharmacy Providers," indicates that the impact of S. 2605 and other similar legislation will save, if anything, far less than the draft CBO estimates. (We will provide the entire study to the Committee under separate cover.) The study used the data from the draft CEO report on the cost savings attributable to S. 2605, validated against fiscal year 1990 data from the Wisconsin Medical Management Information System, hospital group purchasing programs, and the State of Wisconsin procurement office, and then applied it to the top 151 products reimbursed by the Wisconsin Medicaid Program. The institutional sample was 3,050 out of 5,533 institutions.

The study concludes that under the rebate programs, institutional drug costs will increase annually at a rate of over 4%, a total of $403 million, based on an across-the-board increase in drug costs to non-Medicaid programs. When staff and group model health maintenance organizations are considered, that number increases by $37.4 million. Medicare and other Federal programs, which account for about 35% of revenues in organized health-care settings, would have to absorb about $141.5 million in increased drug costs annually. These figures do not include the general inflation rate of pharmaceuticals which ranged between 8% and 11% over the past decade.

When additional data is analyzed, the study presents an even more disturbing scenario of the true cost of these Medicaid rebate programs. Rather than an across-the-board increase, the study postulates that the more likely scenario is that loss of revenue will be made up by increases in the price of sole-source drugs. In fact, ASHP's members confirm that in recent years, the cost of such drugs (e.g., Zidovudine, Tissue Plasminogen Activator, human growth hormone, dantroline, erythropoietin, etc.) have posed significant burdens on institutional drug budgets. In this case, the costs of the Medicaid rebate program could run as high as $735.5 million (including cost increases for health maintenance organizations in the amount of $62.3 million), of which Medicare's share would be approximately $257.3 million. The study also finds that the general public would absorb about a 6% increase in prescription drug costs due solely to a Medicaid rebate program.

Based upon the results of the study, we cannot conclude that enactment of any of these Federal rebate proposals is sound public policy. It makes little sense to control drug costs in the Medicaid program without ensuring that they will not reappear in other programs in which the Federal Government is also a direct or indirect payor for prescription drugs. We would support a more comprehensive approach to find an appropriate mechanism to control drug costs in all publicly funded programs.

IMPACT ON HOSPITAL FORMULARIES

Formularies, which originated over a century ago in hospitals, are the outcome of an ongoing process, the formulary system, and are designed to ensure that patients in a particular setting receive the best possible care by objectively evaluating, selecting, and using those drug products most useful in patient care. (Appendix I, ASHP Statement on the Formulary System). Formulary *systems,* as opposed to formularies, promote better *care* and control costs through a dynamic process in which the medical staff in an organized health care setting, through a pharmacy and therapeutics committee, assesses the drug use process and adopts polices to assure the optimal therapeutic use of drugs. Critical to the operation of the formulary system is a pharmacy and therapeutics committee which functions as an organized line of communication with the medical staff to recommend policies on therapeutic use of drugs and to educate and assist the professional staff on appropriate drug use. (See Appendix II, ASHP Statement on the Pharmacy and Therapeutics Committee). These concepts are well accepted principles among pharmacists, physicians, and hospital administrators and are required by various government standards and national accrediting bodies as hallmarks of "quality health care." In 1990 ASHP's National Survey of Hospital Pharmacy Services showed that over 58% of all hospitals have a "well controlled formulary," one with no duplication of generic drugs and with minimal duplication of therapeutic equivalents. In addition to fostering a high quality of care, formulary systems have a long, documented rack record of controlling drug costs. In the institutional setting, formulary systems have been shown to reduce inpatient drug costs by 30%.

Formulary systems are also used outside the inpatient setting. Hospital-based ambulatory care activities, and particularly managed-care organizations, have implemented effective formulary systems that promote quality care and reduce drug costs. As a result of the implementation of strong formulary systems, managed-care providers estimates savings of between 25–35% of the costs of their annual drug purchases. Approximately 62% of the group model health maintenance organizations (HMO's) and 75% of the staff model HMO's use formularies, and that 90% and 95%, respectively, of the prescriptions filled are for medications on the formulary. Generally, the drugs included in such formularies are those that have a high cost or those for which there are many alternatives available. Classes of drugs that are most likely to be included in the formulary are oral cephalosporins, oral vitamins, other antibiotics, non-steroidal antiinflammatory. Since the number of prescriptions for these products is quite high, it is easy to see that it is a primary means of cost and quality control in the managed-care setting.

One critical element of an effective formulary system is good communications and a close working relationship between pharmacy and the medical staff. Confidence in peer decisions, the ability to effectively discuss committee recommendations, and an awareness that these peer decisions can, and do reflect differences in patient mix, practice sophistication, and other local factors enhance the acceptance and effectiveness of formulary systems.

A. S. 2605 and Adoption of Formulary Concepts. S. 2605 would amend §1927(b) of the Social Security Act to establish a multidisciplinary National Pharmacy and Therapeutics Committee to, *inter alia,* issue a formulary of therapeutic alternatives which would then become the basis for dispensing and reimbursement under state Medicaid plans. We do not believe that this is a workable plan.

We do not think that a national committee that establishes therapeutic equivalents that then become (the perceived) mandated drug product carries with it the necessary local communications and working relationships with practitioners necessary to establish confidence and acceptance of those decisions. In our members' experience, no system without local credibility can be workable. More likely, the National Pharmacy and Therapeutics Committee will be the subject of resentment, which will undermine not only its work, but local formulary systems, too.

Translating what works effectively as a scientific inquiry at the local level to a national level is a Herculean task. The scope of the proposed Committee's charge is immense, and despite its ability to establish panels, it will take years before an adequately funded and staffed entity will be able to fulfill its mission. Moreover, the probability of legal challenges under the Administrative Procedure Act and litigation by pharmaceutical companies makes what is a rational process without the government a very cumbersome process under government auspices.

Therapeutic interchange is a professional concept that works well when physicians and pharmacists inter-relate and communicate on drug use. Therapeutic interchange was initiated, fostered and is more prevalent in organized health care settings, yet our 1988 survey indicates that only 49% of institutions engage in therapeutic interchange with the approval of the medical staff. (This figure gives no indication as to the extent to which therapeutic interchange is practiced at individual hospitals.) While pharmacists certainly have the professional ability to effect therapeutic interchange, this is a professional development that needs interprofessional nurturing, not a governmental mandate.

B. Problems with the Concept of an Open Formulary. Both S. 3029 and H.R. 5589 would amend Section 1902(a) of the Social Security Act by adding new subsection (54)(A) to require that " . . . any formulary or similar restrictions . . . on the coverage of covered outpatient drugs under the [State Medicaid] plan shall permit the coverage of covered outpatient drugs of the manufacturer . . . " which has entered into a rebate agreement under Section 1927(a). As drafted, subsection (54)(A) appears to provide that once a manufacturer has entered into a rebate agreement for its products, any formulary or other restriction that would preclude coverage of an outpatient drug would not be permissible. In essence, once an outpatient drug is "covered," formularies must be open to that drug: once "covered," any pill, tablet, capsule or liquid must be covered for any outpatient/ambulatory service. An "open formulary" means no formulary.

Opening these systems to any and all "outpatient" drugs would:

—Require elimination of ambulatory care formulary systems, though it is beyond cavil that they promote high quality care and control costs;

—Require two formularies, an open or non-formulary for Medicaid beneficiaries and a "closed," and hence more effective, formulary systems for other patients; and

—Promote confusion among organized health care settings and Medicaid administrators about what the language means.

Our concerns are more than "theory" as in recent weeks we have received numerous complaints from our members in a variety of practice settings about industry assertions that under various state Medicaid rebate initiatives formulary systems in hospitals, HMO's and managed care settings will now need to be open to any and all "covered" products.

We strongly urge the Committee to amend subsection (54)(A) to specify and to clarify in the legislative history that once a manufacturer enters into a rebate agreement with the State Plan, elimination of restrictions on eligibility' of an outpatient drug does not affect decisions to include or exclude any' such drug in a formulary in an organized health care setting. We recommend proposed Section 1902(a)(54) be amended as follows:

> (54)(A) provided that, in the case of a manufacturer which has entered into and complies with an agreement under section 1927(a), any formulary or similar restriction (other than a prior authorization program described in section 1927(d)) *operated by the State as part of the State Plan, excluding formularies, formulary systems and similar restrictions operated by any provider, groups of providers or groups of health professionals reimbursed under or pursuant to the State Plan,* on the coverage of outpatient drugs shall permit the coverage of covered outpatient drugs of the manufacturer which are prescribed (on or after April 1, 1991) for a medically accepted indication (as defined in Section 1927(g)(6)). [New language in italic.]

C. Exemption for Organized Settings with Bona Fide Formulary Systems. Organized health care settings are efficient purchasers of drugs and should be exempt from operation of the rebate programs contemplated in these bills. These environments purchase drugs for inpatients and outpatients and use one drug inventory for Medicaid, Medicare and "private pay" patients without distinction. Over 73% of all hospitals belong to a national purchasing group, 24% belong to a regional group and 6% belong to a local purchasing group. To maximize economies of scale, purchasing activities of groups rely on formulary system decisions to minimize duplication of drugs and aggregate drugs for all types of patients in the bid process. The current legislative proposals would undermine those efficient purchasing practices, which benefit the Federal Government, through lower drug costs and reduced reimbursement rates. We urge the Committee to permit organized health care settings to exempt themselves from these rebate programs by adopting the following language amending Section 1927(i)(3) of S. 3026 and Section 1927(g)(3) of H.R. 5589 to read as follows:

> (3) Limiting Definition . . . Such term also does not include any such drug or product *which is purchased by a hospital, health maintenance organization, or managed care program that operates a bona fide formulary system and that aggregates without distinction purchases for use by Title 19 Beneficiaries with its other drug purchases, or* which is used for a medical indication which is not a medically accepted indication.

OTHER PROVISIONS NEEDING AMENDMENT

A. Drug Use Review Provisions Must Be Strengthened. All the proposals add a section, §1927(g), to the Social Security Act requiring state plans to meet standards for both prospective and retrospective drug utilization review. Subsection (g)(2) would require pharmacists to make a reasonable effort or offer to counsel patients about drug therapy and make a reasonable effort to take a medication history from a patient. H.R. 5589 would achieve similar goals, albeit through more general language, through an amendment adding §1927(e) to the Act. Though they need to be strengthened, these provisions are laudable and can be important tools to reduce drug costs.

Pharmacists have a professional responsibility to ensure optimal patient outcomes from drug therapy: it is the ultimate societal purpose that the profession) serves. Pharmacists in organized health care settings have, through programs of drug utilization review, (i.e., "a structured, ongoing quality assurance process to ensure that drugs are used appropriately"), effected that mission. The effort of the DUR activities contemplated in Section 1927(g) can be a well informed patient who exhibits better compliance with drug therapy and better health outcomes. Studies of elderly out-patients receiving counseling, for example, found an 11% decrease in the number of prescriptions and a 39% decrease in the number of medication problems. At stake is not merely the intangible of "better health" but cost savings: drug related hospitalizations and post-hospital treatment cost the health care system over' $5 billion a year.

Given the needs of the Federal budget, strengthening the DUR provisions in Section 1927(g) and 1927(e) seems eminently logical. If only 10% of the costs of drug-related hospitalizations and post-hospital treatment can be saved, the budget will realize substantial, net savings and improve the health of the public as well! ASHP has had a standard for over a decade on the provision of services in the outpatient/ambulatory setting (Appendix III, Statement on the Provision of Pharmaceutical Services in Ambulatory Care Settings) that calls for pharmacists to take medication histories, monitor drug therapy and educate and counsel patients. Our 1984 standard, "Minimum Standard for Ambulatory Care Pharmaceutical Services" (Appendix IV) requires a pharmacist to ensure that, upon dispensing, the patient or his representative receives and understands the information required by our "Guideline on Pharmacist—Conducted Patient Counseling" (Appendix V). Moreover, as our members in managed care and health maintenance organizations have shown, these activities are being done effectively in managed care settings.

We therefore propose that the Committee capitalize on these potential savings by requiring, as state minimum standards, that pharmacists keep patient profiles (set forth in §1927(g)(2)(B)(iii) and dispense a drug only after a patient has been counseled, in person or by telephone. We also urge incorporation of ASHP standards into the statute as the basic standard for counseling and patient profiles. Specifically, we urge Section 1927(e) in H.R. 5589 and §1927(g) in S. 3026 be replaced with the following adapted from language in S. 3026.

. . . Drug Use Review . . .

. . . (2) Description of Program . . .

(A) PROSPECTIVE DRUG REVIEW—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to the patient, typically at the point-of-sale or point of distribution. Each pharmacist shall use the compendia referred to in subsection (l)(6) as its source of standards for such review.

"(ii) As part of the State's prospective drug use review program under this subparagraph, applicable State law shall establish standards for patient counseling by pharmacists which includes at least the following:

"(I) The pharmacist must **[offer to]** discuss with each patient or caregiver (in person, whenever practicable, or through access to a telephone service which is toll-free for long distance calls) who presents a new prescription the following matters, *and other matters* which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant: **[including at least the following:]**

"(a) The name and description of the medication.

"(b) The route, *dosage form,* dosage, route of administration, and continuity of drug therapy.

"(c) Special directions *and precautions for preparation and administration and* use by the patient. **[as deemed necessary by the pharmacist]**

"(d) Common severe *side or* adverse effects or interactions and *therapeutic contraindications* that may be encountered, *including their avoidance,* and the action required if they occur.

"*(e) Techniques for self-monitoring drug therapy.*

"*(f) Proper storage.*

"*(g) Prescription refill information.*

"*(h) Action to be taken in the event of a missed dose.*

"(II) The pharmacist must obtain, record and maintain at least the following patient information:

"(a) Patient name, address, telephone number, date of birth (or age), and gender.

"(b) Patient history where significant, including chronic disease state or states, known allergies and drug reactions, and as current of a comprehensive list of medications and relevant devices as possible.

"(c) Pharmacist comments.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when a patient or caregiver *affirmatively* refuses such consultation. [Old language in brackets in bold, new language in italic]

B. Proposed HMO Reporting Requirement in H.R. 5589 is Punitive. H.R. 5589 includes an amended Section 1903(m)(2)(A) of the Social Security Act which would require HMO's to report quarterly on the identity and dosages of covered outpatient drugs prescribed. S. 3026 contains no comparable provision.

We strongly oppose this provision as unnecessary and unfairly punitive. First, the Secretary of Health and Human Services has existing authority under 42 U.S.C. 1396 to inspect the books and records of health maintenance organizations. Quarterly reporting of prescribed drugs is an immensely burdensome requirement and makes no positive contribution to the bill; HMO's are singled out for reporting when no other group against whom the "best price" standard is measured must report similar data. Finally, we note that under the risk management contracts typically assumed by HMO's, reporting of this information is virtually irrelevant to the objectives of the bill.

CONCLUSION

Mr. Chairman, it is difficult to be in support of a principle but opposed to its execution, but that is precisely where we find ourselves in this case. We agree that Medicaid, and indeed, all federally funded health programs, deserve a better break on drug prices and that price breaks, whether in the form of rebates or through effective operation of formulary systems by providers ace not inconsistent with high quality care. We do not believe that execution of these principles can be supported because:

—by only addressing part of the drug cost issue these proposals will *not* save money;
—the bills do not adequately account for nor do they adequately protect existing formulary systems; and
—the bills miss opportunities for substantial cost savings by weak drug utilization review provisions.

We believe that the objective sought to be obtained by these bills must not be lost or abandoned, but that precipitous legislative action will result in an unworkable program that will discredit those objectives in the long-term. We urge more thorough and careful drafting of a program that will achieve and advance efficient purchasing of drugs and further enhance the quality of care provided to both Medicaid and Medicare beneficiaries and all other people who use the health care system.

ASHP Statement on the Formulary System

Preamble

The care of patients in hospitals and other health-care facilities is often dependent on the effective use of drugs. The multiplicity of drugs available makes it mandatory that a sound program of drug usage be developed within the institution to ensure that patients receive the best possible care.

In the interest of better patient care, the institution should have a program of objective evaluation, selection, and use of medicinal agents in the facility. This program is the basis of appropriate, economical drug therapy. The formulary concept[a] is a method for providing such a program and has been utilized as such for many years.

To be effective, the formulary system must have the approval of the organized medical staff, the concurrence of individual staff members, and the functioning of a properly organized pharmacy and therapeutics committee[b] of the medical staff. The basic policies and procedures governing the formulary system should be incorporated in the medical staff bylaws or in the medical staff rules and regulations.

The pharmacy and therapeutics committee represents the official organizational line of communication and liaison between the medical and pharmacy staffs. The committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as to the normal administrative approval process.

This committee assists in the formulation of broad professional policies relating to drugs in institutions, including their evaluation or appraisal, selection, procurement, storage, distribution, and safe use.

Definition of Formulary and Formulary System

The *formulary* is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of the medical staff.[c]

The *formulary system* is a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care. Only those so selected are routinely available from the pharmacy. The formulary system is thus an important tool for assuring the quality of drug use and controlling its cost. The formulary system provides for the procuring, prescribing, dispensing, and administering of drugs under either their nonproprietary or proprietary names in instances where drugs have both names.

Guiding Principles

The following principles will serve as a guide to physicians, pharmacists, nurses, and administrators in hospitals and other facilities utilizing the formulary system:

1. The medical staff shall appoint a multidisciplinary pharmacy and therapeutics committee and outline its purposes, organization, function, and scope.
2. The formulary system shall be sponsored by the medical staff based on the recommendations of the pharmacy and therapeutics committee. The medical staff should adapt the principles of the system to the needs of the particular institution.
3. The medical staff shall adopt written policies and procedures governing the formulary system as developed by the pharmacy and therapeutics committee. Action of the medical staff is subject to the normal administrative approval process. These policies and procedures shall afford guidance in the evaluation or appraisal, selection, procurement, storage, distribution, safe use, and other matters relating to drugs and shall be published in the institution's formulary or other media available to all members of the medical staff.
4. Drugs should be included in the formulary by their nonproprietary names, even though proprietary names may be in common use in the institution. Prescribers should be strongly encouraged to prescribe drugs by their nonproprietary names.
5. Limiting the number of drug entities and drug products routinely available from the pharmacy can produce substantial patient-care and (particularly) financial benefits. These benefits are greatly increased through the use of *generic equivalents* (drug products considered to be identical with respect to their active components; e.g., two brands of tetracycline hydrochloride capsules) and *therapeutic equivalents* (drug products differing in composition or in their basic drug entity that are considered to have very similar pharmacologic and therapeutic activities; e.g., two different antacid products or two different alkylamine antihistamines). The pharmacy and therapeutics committee must set forth policies and procedures governing the dispensing of generics and therapeutic equivalents. These policies and procedures should include the following points:
    - That the pharmacist is responsible for selecting, from available generic equivalents, those drugs to be dispensed pursuant to a physician's order for a particular drug product.
    - That the prescriber has the option, at the time of prescribing, to specify the brand or supplier of drug to be dispensed for that particular medication order/prescription. The prescriber's decision should be based on pharmacologic or therapeutic considerations (or both) relative to that patient.
    - That the pharmacy and therapeutics committee is responsible for determining those drug products and entities (if any) that shall be considered therapeutic equivalents. The conditions and

procedures for dispensing a therapeutic alternative in place of the prescribed drug shall be clearly delineated.

6. The institution shall make certain that its medical and nursing staffs are informed about the existence of the formulary system, the procedures governing its operation, and any changes in those procedures. Copies of the formulary must be readily available and accessible at all times.
7. Provision shall be made for the appraisal and use of drugs not included in the formulary by the medical staff.
8. The pharmacist shall be responsible for specifications as to the quality, quantity, and source of supply of all drugs, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients. When applicable, such products should meet the standards of the *United States Pharmacopeia*.

Recommendation

A formulary system, based on these guiding principles, is important in drug therapy in institutions. In the interest of better and more economical patient care, its adoption by medical staffs is strongly recommended.

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[a] The formulary system is adaptable for use in any type of health-care facility and is not limited to hospitals.

[b] For additional information, see the "ASHP Statement on the Pharmacy and Therapeutics Committee" (*Am J Hosp Pharm.* 1978; 35:813-4).

[c] For additional information, see the "ASHP Guidelines for Hospital Formularies" (*Am J Hosp Pharm.* 1978; 35:326-8).

Approved by the ASHP House of Delegates, June 7, 1983. Approved by the ASHP Board of Directors, November 18, 1982. Developed by the ASHP Council on Clinical Affairs. Supersedes the "ASHP Statement of Guiding Principles on the Operation of the Hospital Formulary System" approved by the Board of Directors, January 10, 1964.

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APPENDIX II

ASHP Statement on the Pharmacy and Therapeutics Committee

The multiplicity of drugs available and the complexities surrounding their safe and effective use make it necessary for hospitals to have an organized, sound program for maximizing rational drug use. The pharmacy and therapeutics committee, or its equivalent, is the organizational keystone of this program.

The pharmacy and therapeutics committee is an advisory group of the medical staff and serves as the organizational line of communication between the medical staff and pharmacy department. This committee is composed of physicians, pharmacists, and other health professionals selected with the guidance of the medical staff. It is a policy-recommending body to the medical staff and the administration of the hospital on matters related to the therapeutic use of drugs.

Purposes

The primary purposes of the pharmacy and therapeutics committee are:

1. Advisory. The committee recommends the adoption of, or assists in the formulation of, policies regarding evaluation, selection, and therapeutic use of drugs in hospitals.
2. Educational. The committee recommends or assists in the formulation of programs designed to meet the needs of the professional staff (physicians, nurses, pharmacists, and other health-care practitioners) for complete current knowledge on matters related to drugs and drug use.

Organization and Operation

While the composition and operation of the pharmacy and therapeutics committee might vary from hospital to hospital, the following generally will apply:

1. The pharmacy and therapeutics committee should be composed of at least three physicians, a pharmacist, a nurse, and an administrator. Committee members are appointed by a governing unit or elected official of the organized medical staff.
2. A chairman from among the physician representatives should be appointed. A pharmacist usually is designated as secretary.
3. The committee should meet regularly, at least six times per year, and more often when necessary.
4. The committee should invite to its meetings persons within or outside the hospital who can contribute specialized or unique knowledge, skills, and judgments.
5. An agenda and supplementary materials (including minutes of the previous meeting) should be prepared by the secretary and submitted to the committee members in sufficient time before the meeting for them to review the material properly.
6. Minutes of the committee meetings should be prepared by the secretary and maintained in the permanent records of the hospital.
7. Recommendations of the committee shall be presented to the medical staff or its appropriate committee for adoption or recommendation.
8. Liaison with other hospital committees concerned with drug use (e.g., infection control and medical audit) shall be maintained.

Functions and Scope

The basic organization of the hospital and medical staffs will determine the functions and scope of the pharmacy and therapeutics committee. The following list of committee functions is offered as a guide:

1. To serve in an advisory capacity to the medical staff and hospital administration in all matters pertaining to the use of drugs (including investigational drugs).
2. To develop a formulary of drugs accepted for use in the hospital and provide for its constant revision. The selection of items to be included in the formulary will be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic drug type, drug entity, or drug product.
3. To establish programs and procedures that help ensure cost-effective drug therapy.
4. To establish or plan suitable educational programs for the hospital's professional staff on matters related to drug use.
5. To participate in quality-assurance activities related to distribution, administration, and use of medications.
6. To review adverse drug reactions in the hospital.
7. To initiate or direct (or both) drug use review programs and studies and review the results of such activities.
8. To advise the pharmacy in the implementation of effective drug distribution and control procedures.
9. To make recommendations concerning drugs to be stocked in hospital patient-care areas.

Approved by the ASHP House of Delegates, June 6, 1984. Approved by the ASHP Board of Directors, November 17-18, 1983. (The previous version was approved by the House of Delegates, May 15, 1978.) Revised by the ASHP Council on Clinical Affairs.

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ASHP Statement on the Provision of Pharmaceutical Services in Ambulatory Care Settings

The concern for increasing access to health-care services and containing health-care costs has led to increased demands for ambulatory patient-care services in organized health-care settings. Ambulatory care encompasses the provision of health-care services and education to patients who are able to seek medical attention, yet do not require admission to an institution for health-care needs. To meet these needs, organized settings for delivery of ambulatory health care are being created within institutional structures as well as in satellite clinics and noninstitutional ambulatory health-care systems, including group medical practices and health maintenance organizations.

This expansion of health care into ambulatory settings has been accompanied by an evolution of patient-oriented pharmaceutical services that extend beyond traditional preparation and dispensing of medications. Many of the activities outlined in the American Society of Hospital Pharmacists' "Statement on Clinical Functions in Institutional Pharmacy Practice"[1] have been adapted to a variety of ambulatory care settings. The scope of these activities may vary with practice site but commonly include:

1. Obtaining and documenting patient medication histories.
2. Monitoring the safety and efficacy of drug therapy through the maintenance of medication profiles.
3. Providing drug information to prescribers and other health-care practitioners.
4. Assisting prescribers in the proper selection and adjustment of drug therapy through application of pharmacokinetic and other principles.
5. Utilizing assessment skills in the management of acute and chronic diseases and providing appropriate referrals to other health-care providers.
6. Detecting and reporting adverse drug reactions, interactions, and noncompliant patient behavior.
7. Educating and counseling patients and the general public in the proper use of medications.
8. Participating in drug use reviews, patient-care audits, and clinical drug investigations.
9. Participating in the education of health-care providers.
10. Supervising the storage, preparation, dispensing, and administration of medications in the patient-care area.
11. Developing systems for the delivery of pharmacy services in the institutional setting and the community.
12. Developing and utilizing systems for fiscal management and reimbursement.

Directors of pharmacy services in institutions and pharmacists in noninstitutional settings have the responsibility to develop and maintain comprehensive pharmaceutical services commensurate with the individual needs of each health-care setting and to evaluate and document the health-care benefits of such services. The American Society of Hospital Pharmacists recognizes and supports the development and implementation of comprehensive ambulatory pharmaceutical services in organized health-care settings.

Reference

1. American Society of Hospital Pharmacists. ASHP statement on clinical functions in institutional pharmacy practice. *Am J Hosp Pharm.* 1978; 35:813.

Developed by the ASHP Council on Clinical Pharmacy and Therapeutics. Approved by the ASHP Board of Directors, March 20, 1980, and by the ASHP House of Delegates, April 21, 1980.

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Reprinted from the *Am J Hosp Pharm.* 1980; 37:1096.

APPENDIX IV

ASHP Guidelines: Minimum Standard for Ambulatory Care Pharmaceutical Services

Services to ambulatory patients are an important part of many institutional pharmacy programs. The need for such services probably will increase substantially in the 1980s.

The Society has identified 12 activities in which institutional pharmacists will be involved in the ambulatory care setting.[1] However, providing all these services in all institutions at all times is not feasible. At a minimum, ambulatory patients require certain critical pharmaceutical services. The essential elements of any ambulatory care pharmaceutical service program are as follows:

1. The ambulatory care pharmacy program must be directed by a qualified pharmacist.
2. The appropriateness of the choice of drug and its dosage, route of administration, and amount must be verified by the pharmacist. This will require the maintenance of medication profiles for patients routinely treated at the institution to prevent duplicate drug therapies and the use of contraindicated drugs.
3. All medications dispensed to patients will be completely and correctly labeled and packaged in accordance with all applicable regulations and accepted standards of practice.
4. On dispensing a new medication (to the patient), the pharmacist will ensure that the patient or his representative receives and understands all information required for proper use of the drug.[2]
5. All drugs in ambulatory care service areas will be properly controlled.[3]

The American Society of Hospital Pharmacists believes that patients in all ambulatory care facilities should expect these five pharmaceutical services, without exception.

References

1. American Society of Hospital Pharmacists. ASHP statement on the provision of pharmaceutical services in ambulatory care settings. *Am J Hosp Pharm.* 1980; 37:1095.
2. American Society of Hospital Pharmacists. ASHP statement on pharmacist-conducted patient counseling. *Am J Hosp Pharm.* 1976; 33:644.
3. American Society of Hospital Pharmacists. ASHP guidelines on hospital drug distribution and control (with references). *Am J Hosp Pharm.* 1980; 37:1097-103.

Approved by the ASHP Board of Directors, November 19, 1981.

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Reprinted from the *Am J Hosp Pharm.* 1982; 39:316.

APPENDIX V

ASHP Guidelines on Pharmacist-Conducted Patient Counseling

Safe and effective drug therapy most frequently occurs when patients are well informed about medications and their use. Knowledgeable patients exhibit increased compliance with drug regimens, resulting in improved therapeutic outcomes. Therefore, pharmacists, as well as other health professionals, have a responsibility to inform patients properly about their drug therapy.

Pharmacists' drug consultations with patients should be aimed at improving therapeutic outcomes by maximizing proper use of medications. Pharmacists, in collaboration with other health team members when appropriate, must determine the specific information and counseling required in each patient-care situation.

Using suitable oral, written, or audiovisual communication techniques and methods, the pharmacist should inform, educate, and counsel patients (or their representative or guardian) about the following items for each medication in the patient's drug regimen:

1. Name [trademark, generic, common synonym, or other descriptive name(s)].
2. Intended use and expected action.
3. Route, dosage form, dosage, and administration schedule.
4. Special directions for preparation.
5. Special directions for administration.
6. Precautions to be observed during administration.
7. Common side effects that may be encountered, including their avoidance and the action required if they occur.
8. Techniques for self-monitoring of drug therapy.
9. Proper storage.
10. Potential drug-drug or drug-food interactions or other therapeutic contraindications.
11. Prescription refill information.
12. Action to be taken in the event of a missed dose.
13. Any other information peculiar to the specific patient or drug.

These 13 points are applicable to both prescription and nonprescription drugs. In addition, pharmacists must counsel patients in the proper selection of nonprescription drugs as well as when and if they should be used.

Approved by the ASHP Board of Directors, November 17-18, 1983. Supersedes an earlier version approved by the Board of Directors in 1975. Developed initially and revised by the ASHP Council on Clinical Affairs.

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Reprinted from the *Am J Hosp Pharm.* 1984; 41:331.

Statement of the Arthritis Foundation

The Arthritis Foundation supports Senator Pryor's ultimate goal that pharmaceutical companies share in the burden of Medicaid cost containment by lowering the cost of medications to state Medicaid programs. We believe that this can be accomplished by ensuring that drug pricing discounts be given to state Medicaid programs as they are currently offered to other large government entities and bulk purchasers.

While we strongly endorse prudent purchasing, we have serious reservations about therapeutic substitution and have a long history of opposition to this practice. The reasons for this opposition are as follow:

(a) Therapeutic substitution is counter to the basic principles of drug therapy since not all patients respond in the same way to the same drug—both in terms of therapeutic response and adverse reactions. There are individual differences among patients that can lead to an unexpected response when one drug is substituted for another.

(b) People with arthritis have a chronic disease often requiring multiple drug therapy both sequentially arid in combination. Thus, the potential for toxicity and negative drug interaction is high.

(c) Due to the chronic nature of arthritis, it is imperative that therapy be individualized by a physician who has intimate knowledge of the patient's medical history.

(d) All patients with arthritis deserve access to the same quality medical care including medication.

IN SUMMARY

The Arthritis Foundation strongly endorses efforts made toward cost containment for Medicaid programs. At the same time we have grave concerns, as well as a history of opposition, regarding legislative efforts to achieve these savings by means of therapeutic substitution. We therefore oppose the OMB/Darman proposal which mandates therapeutic substitution and oppose S. 2605 insofar as it establishes a mechanism for therapeutic substitution which threatens access to medication for state Medicaid recipients.

Statement of the Delaware Epilepsy Association

On behalf of the Delaware Epilepsy Association, I am pleased to submit testimony for the record of hearings held by the Senate Finance Committee Subcommittee on Health for the Family and the Uninsured regarding S. 2605, the OMB Proposal, as well as S. 3029 and H.R. 5589—all pertaining to the Medicaid prescription drug program.

1. Therapeutic substitution contained in S. 2605 and the OMB proposal are completely unacceptable because drugs in the same class often have different effects. There are important differences between drugs in the same therapeutic class and substituting one drug for another may well result in people with epilepsy either experiencing seizures or toxic side affects. Physicians, after close examination of their patients know what their patients need. It is totally unacceptable for a pharmacist to second guess what is appropriate treatment for particular individual with epilepsy as the OMB proposal would permit.

We are opposed to the substitution of any prescribed anticonvulsant drug (whether generic or brand) especially without the knowledge of the patient and the attending physician. Our concerns stems from the adverse experiences which have occurred to people with epilepsy when State Medicaid agencies, hospitals and other health care institutions have imposed mandatory substitution programs in an attempt to reduce health care costs.

2. Requiring physicians to obtain prior authorization before prescribing their drug of choice adds additional administrative burden to a decision which should be that of the physician alone, based on what is best for the individual patient. Any plan which requires that decisions of therapeutic selectivity be based on cost of the drug or on the ability of a manufacturer to provide a rebate to Medicaid is unacceptable. Bill S. 3029 and House Resolution 5589 both require such provisions.

3. The Association feels that all four proposals will increase bureaucratic red tape and will not save a significant amount of money. Any money saved would be at the expense of those individuals who count the most, the Medicaid recipient. Manufacturer rebate proposals do not produce significant cost savings. High administrative

costs coupled with the fact that many multiple source drugs are already subject to price control limits the cost saving potential of a rebate program.

4. The Association believes restricting the access to pharmaceuticals is detrimental to Medicaid recipients for the following reasons:

> As stated above, the substitution of drugs for persons with epilepsy who are Medicaid patients could be disastrous and would impede investment in pharmaceutical research.

Medicaid recipients in Delaware have always had unrestricted access to all FDA approved drugs. Any measure that would limit access of drugs to Medicaid recipients would have the effect of reducing the quality of care available to our poorest citizens.

We understand the budgetary pressures facing members of the U.S. Congress, but the budget should not be balanced at the expense of so many people.

On behalf of the Delaware Epilepsy Association, I urge you to oppose all four proposals mentioned that would so adversely affect so many Delawareans. Thank you.

STATEMENT OF THE DETROIT ASSOCIATION OF BLACK ORGANIZATIONS

Mr. Chairman and distinguished members of the Subcommittee, my name is Horace L. Sheffield, Jr., and I am Executive Director of the Detroit Association of Black Organizations (DABO). I am most appreciative for this opportunity to submit testimony on behalf of DABO in respect to Senate Bill 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990, and other proposals which would have a direct impact on the Medicaid Drug Program.

DABO is a coalition of more than 190 neighborhood groups, community association, city-wide agencies, and affiliates of national organizations. We are a moving force in Detroit as well as throughout Michigan. DABO, organized in 1979, is committed to equal opportunity for all citizens through comprehensive programs that meet our community's needs, including education, employment training, housing, and with respect to this pending legislation—health care We, collectively and individually, have been in the forefront of championing these important concerns as well as effectively addressing these needs throughout Detroit.

U. S. Senate Bill 2605, as a budget-cutting measure, shamefully seeks to save money in the Medicaid Program at the expense of the elderly, the poor, the children and the disabled. It would mandate that pharmacists substitute the cheapest alternative drug when filling prescriptions for Medicaid patients. The pharmacists is required to make a "diligent effort" to call the doctor about the change. If the doctor can't be reached then, as provided by S. 2605, the pharmacist is mandated to give the Medicaid subscriber a "three-day-supply" of the cheapest alternative drug.

The "three-day-supply" provision would certainly force Medicaid patients to return to a pharmacy in three days. This so because even with a "diligent effort," there would be hundreds of thousands of cases where this pharmacist would not reach the doctor. This would present a real hardship since its estimated that only 10% of Medicaid patients have their own transportation.

We are, therefore, strongly opposed to this bill. The harsh restrictions it places on Medicaid drug availability will surely result in second-class medicine for the elderly, the poor, the children and the disabled. While originally touted as a cost containment measure, S. 2605 could end up costing taxpayers more money through additional bureaucracy to administer such a program, and the increased need for more expensive hospitalization or surgery when new and improved drugs are denied to Medicaid patients.

It merits noting that black Americans suffer from tremendous disparities in medical afflictions: hypertension; cardiovascular disease; diabetes; sickle cell anemia; and others. What's more, black Americans also suffer tremendous disparities when it comes to health coverage and access to quality treatment. S. 2605 would cleanly make these disparities even worse.

Any effort to change Medicaid drug programs should surely include these points: 1. Medicaid patients must be assured maximum availability of medically necessary drugs; 2. the elderly, the poor, the children and the disabled should not bear the, burden of reducing Medicaid prescription drug costs; 3. Medical necessity, riot price should determine which drugs are covered by Medicaid; and 4. Medicaid recipients should be afforded the same availability of quality health care and medically necessary drugs as non-Medicaid patients. There should not be double standard of health care for America's aged, sick and disabled—regardless of ability too pay.

From our perspective, one of a front-line community based organization, the implementation of the provisions of Senator Pryor's bill could prove not only a bureaucratic nightmare, but one which poses grievous health risks for all Medicaid patients. The risks include: Cheap, inappropriate or inferior quality drugs which may threaten the very lives of the patients. Delays in access to medically required drugs, given that treatment is often received in emergency rooms and walk-in clinics, with no consistent family physician to monitor the patient.

For these reasons, as well as that of genuine fairness-please do not deny quality health care to those least able to obtain such care, our nation's poor, sick and disabled—through imposition of further prescription drug restrictions.

Thank you, Mr. Chairman.

DETROIT MEDICAL SOCIETY,
Detroit, MI, September 7, 1990.

Ms. LAURA WILCOX, *Hearing Administrator,*
Senate Finance Committee,
Washington, DC.

Re: S. 2605—Therapeutic Substitution for Medicaid Recipients

Dear Ms. Wilcox: I am forwarding this written statement to you to have it included in the printed record of the Finance Subcommittee on Health for Families and the Uninsured, to be held on Monday, September 17, 1990.

This statement comes on behalf of the 350 African-American physicians that comprise the membership of the Detroit Medical Society. Our members practice in and around the City of Detroit. The majority of our membership's patient population is made up of people who are Medicaid recipients.

We are concerned about the serious, deleterious effect that this bill, if enacted into law, will have on the health of our patients.

This bill, for economic reasons, promotes the use of the cheapest, rather than the best drug for a particular medical condition. Therapy should be individualized, and the arbitrary abandoning of appropriate therapy for purely economic reasons does nothing but promote a second-class method of rationing health care.

The attending physician who has taken a careful comprehensive history and done a thorough examination is the only person knowledgeable about all the complex factors that come into play to support his/her diagnostic hypothesis Therefore, this physician should be the only one to select a medication for the individual patient's problem.

The bill allows that a National Panel would establish a formulary for "therapeutic alternate'," to be used when a "higher priced" medication is prescribed. This formulary for "therapeutic alternates" is to be based on "Superior Economic Advantage" (i.e., cheaper price). This is very risky for the patient because even though these drugs are expected to have similar therapeutic effects, they are different chemically.

Unlike generic prescribing where the same chemical (medication) is given, just a different brand name; here we are substituting an entirely different chemical to accomplish the same goal. (Sort of like substituting a sail boat for a motor boat: they accomplish the same goal, travel on water, but do it in an entirely different manner. Under ideal conditions with a trained sailor, they both work, but change the conditions and one certainly has distinct advantages over the other).

Primary in our concern, and we ask that you also please consider this in your opposition to this bill, is what the ultimate effect this bill will have on the patient. The vast majority of our patients, better than 90%, are African-American. It is a known fact that African-Americans already suffer from a tremendous disparity in health status, health coverage, and access to health care

Numerous studies have been done documenting the greater occurrence of hypertension (and its deleterious effects such as renal failure, stroke, heart disease, etc.), diabetes (and its complications), cancer (breast, lung, esophageal, and prostate) in the African-American community.

To take just one of these diseases, e.g., hypertension: The African-American with hypertension is a different disease entity than the White American. The same medication in the same dosage regimen does not always control his/her blood pressure to the same degree.

Also consideration must be given to the side effects that are caused by some of these medications. Again, using the example of hypertension in the African-American population.

One of the major side effects of antihypertensive medications as a class is impotence. This side effect seems to occur much more frequently, and to a greater degree, in the African-American male, than in the White male. When we further note that hypertension as a disease strikes the Black male at a younger age generally than the White male (30–50 age range), then the psychosocial consequences of this side effect are devastating.

The medications to control his blood pressure oftentimes has to be changed until a happy balance can be reached between blood pressure control and a normal existence (i.e., minimization of side effects = impotence).

If this bill is adopted, a medication may be given to him purely based on its cheaper price if this medicine causes a major side effect such as impotence, then he will not take it. If he does not take it, then his hypertension is not controlled thereby leading to renal failure and/or a stroke. Now we have a young man of 35 in renal failure, requiring long term dialysis and/or institutional care—what is the cost savings in this scenario?

What we ask is that you please take a look at what this bill will do to the Medicaid patient, not just the supposed savings to the system.

Another provision in the bill that we find disturbing is patient privacy. As the bill states, if the medication the physician has prescribed is not on the formulary, the pharmacist is required to change it to one that is on the formulary.

To do this, he must then discuss the patient's condition and medical history with the doctor to decide on an adequate therapeutic substitute. This is definitely an intrusion into the time honored and legally required doctor-patient privilege of privacy. Should poverty cause one to lose one of the basic human rights we have as Americans—that is privileged privacy between a patient and his/her physician.

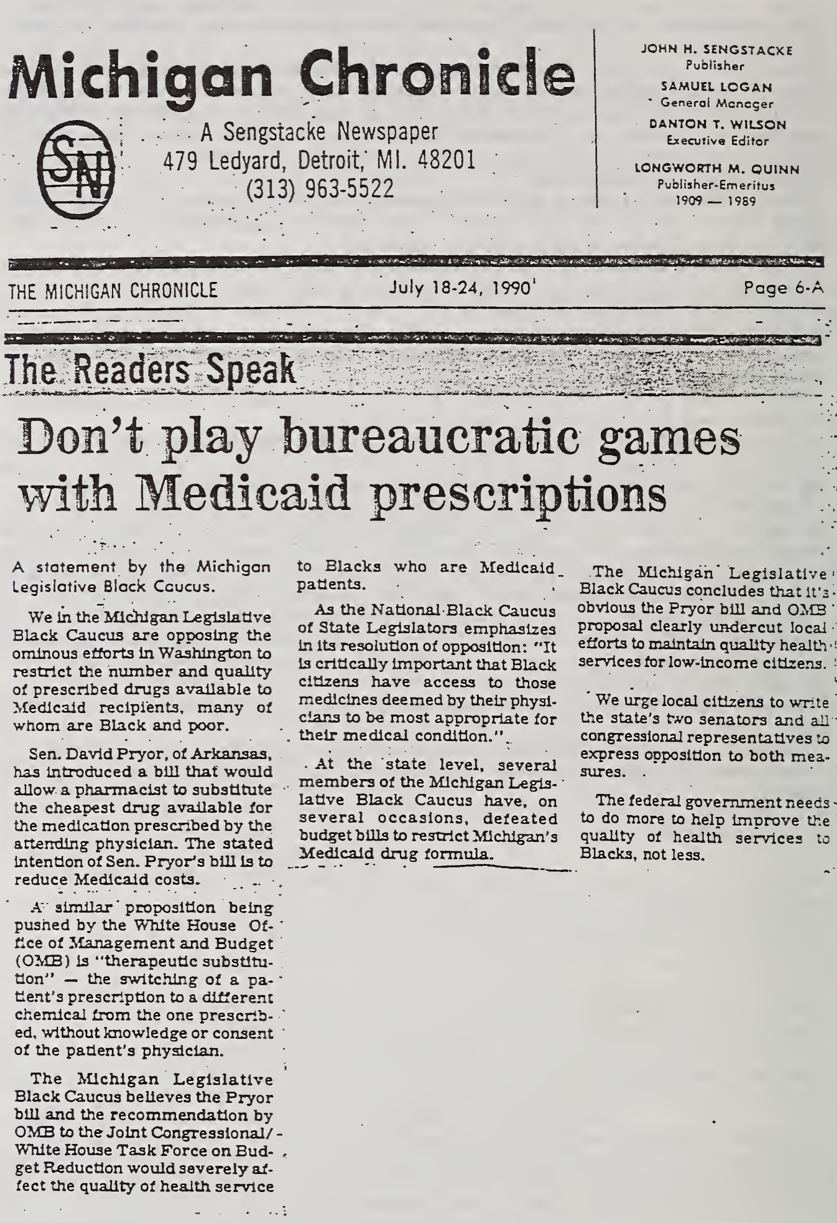
What if the doctor cannot be reached? There are provisions in this bill for the pharmacist to take patient histories. Unless pharmacists are going to be required to have private consultation rooms in the drug stores, where will this be done—out in the open, over the drug counter?

No one, Black or White, rich or poor, should reduce themselves to such an indignity.

Please do not let the disguise of cost savings cause the African-American to become more disenfranchised and forced further into a status of Second Class Citizenship.

Yours truly,

James K. Johnson, M.D., F.A.C.S.,
President, Detroit Medical Society



Michigan Chronicle

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THE MICHIGAN CHRONICLE July 18-24, 1990 Page 6-A

The Readers Speak

Don't play bureaucratic games with Medicaid prescriptions

A statement by the Michigan Legislative Black Caucus.

We in the Michigan Legislative Black Caucus are opposing the ominous efforts in Washington to restrict the number and quality of prescribed drugs available to Medicaid recipients, many of whom are Black and poor.

Sen. David Pryor, of Arkansas, has introduced a bill that would allow a pharmacist to substitute the cheapest drug available for the medication prescribed by the attending physician. The stated intention of Sen. Pryor's bill is to reduce Medicaid costs.

A similar proposition being pushed by the White House Office of Management and Budget (OMB) is "therapeutic substitution" — the switching of a patient's prescription to a different chemical from the one prescribed, without knowledge or consent of the patient's physician.

The Michigan Legislative Black Caucus believes the Pryor bill and the recommendation by OMB to the Joint Congressional/White House Task Force on Budget Reduction would severely affect the quality of health service to Blacks who are Medicaid patients.

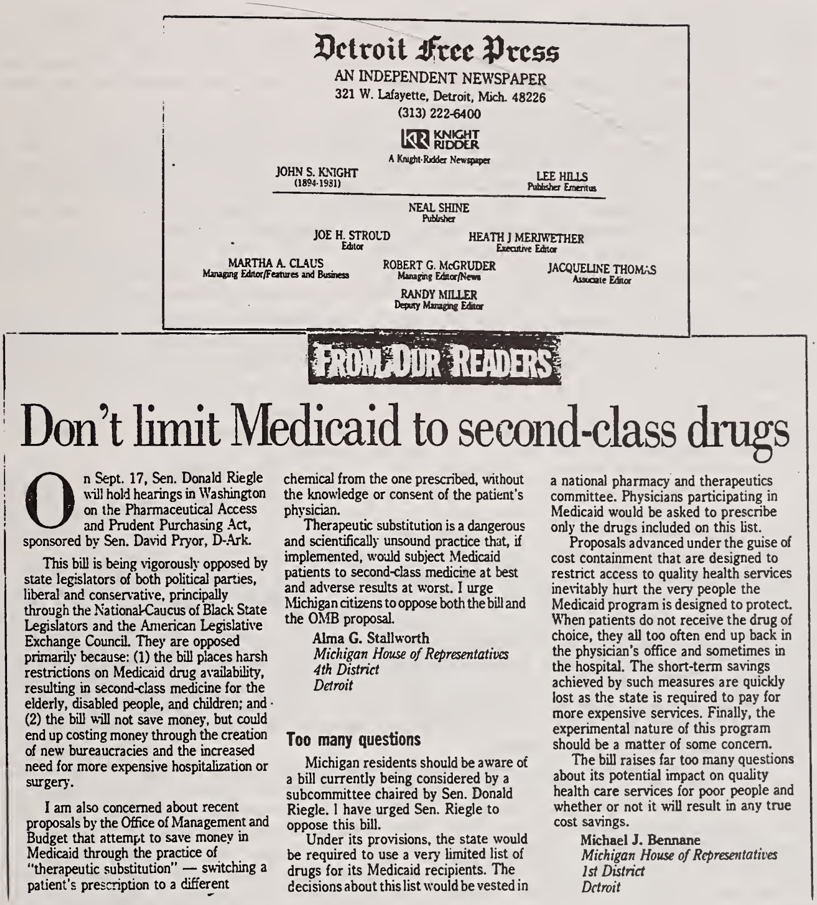
As the National Black Caucus of State Legislators emphasizes in its resolution of opposition: "It is critically important that Black citizens have access to those medicines deemed by their physicians to be most appropriate for their medical condition."

At the state level, several members of the Michigan Legislative Black Caucus have, on several occasions, defeated budget bills to restrict Michigan's Medicaid drug formula.

The Michigan Legislative Black Caucus concludes that it's obvious the Pryor bill and OMB proposal clearly undercut local efforts to maintain quality health services for low-income citizens.

We urge local citizens to write the state's two senators and all congressional representatives to express opposition to both measures.

The federal government needs to do more to help improve the quality of health services to Blacks, not less.



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FROM OUR READERS

Don't limit Medicaid to second-class drugs

On Sept. 17, Sen. Donald Riegle will hold hearings in Washington on the Pharmaceutical Access and Prudent Purchasing Act, sponsored by Sen. David Pryor, D-Ark.

This bill is being vigorously opposed by state legislators of both political parties, liberal and conservative, principally through the National-Caucus of Black State Legislators and the American Legislative Exchange Council. They are opposed primarily because: (1) the bill places harsh restrictions on Medicaid drug availability, resulting in second-class medicine for the elderly, disabled people, and children; and (2) the bill will not save money, but could end up costing money through the creation of new bureaucracies and the increased need for more expensive hospitalization or surgery.

I am also concerned about recent proposals by the Office of Management and Budget that attempt to save money in Medicaid through the practice of "therapeutic substitution" — switching a patient's prescription to a different chemical from the one prescribed, without the knowledge or consent of the patient's physician.

Therapeutic substitution is a dangerous and scientifically unsound practice that, if implemented, would subject Medicaid patients to second-class medicine at best and adverse results at worst. I urge Michigan citizens to oppose both the bill and the OMB proposal.

Alma G. Stallworth
Michigan House of Representatives
4th District
Detroit

Too many questions

Michigan residents should be aware of a bill currently being considered by a subcommittee chaired by Sen. Donald Riegle. I have urged Sen. Riegle to oppose this bill.

Under its provisions, the state would be required to use a very limited list of drugs for its Medicaid recipients. The decisions about this list would be vested in a national pharmacy and therapeutics committee. Physicians participating in Medicaid would be asked to prescribe only the drugs included on this list.

Proposals advanced under the guise of cost containment that are designed to restrict access to quality health services inevitably hurt the very people the Medicaid program is designed to protect. When patients do not receive the drug of choice, they all too often end up back in the physician's office and sometimes in the hospital. The short-term savings achieved by such measures are quickly lost as the state is required to pay for more expensive services. Finally, the experimental nature of this program should be a matter of some concern.

The bill raises far too many questions about its potential impact on quality health care services for poor people and whether or not it will result in any true cost savings.

Michael J. Bennane
Michigan House of Representatives
1st District
Detroit

STATEMENT OF THE HARRIS COUNTY HEALTH DEPARTMENT

Mr. Chairman, my name is Robert H. Barr. I am a physician and have a degree in pharmacy. I have been assistant director of the Harris County Health Department since February 1987, and I am chairman of the subcommittee of the Medical Care Advisory Committee that recommends which drugs should be included on the state's Medicaid formulary.

Since S. 2605 and other proposals before your committee would require Texas to adopt a Medicaid formulary written by consultants in Washington), D.C., I felt it was necessary to defend the present system and the program that's now in place in Texas. It works very well and consequently is supported by most of the state's physicians. I am afraid that if the restricted formulary envisioned in S. 2605 is forced on our physicians, there won't be any Medicaid providers left in Texas.

Recently, the Texas Department of Human Services sent to your committee its comments on S. 2605, developed by the Deputy Commissioner for Contracted Client Services, Dr. Donald L. Kelley. Let me summarize these comments briefly:

1. As a charge-based system, the proposal is inherently inflationary. Pharmacists' customary charges are often far higher on drugs, particularly generic drugs, than is warranted by the ingredient costs. Mandating such a system in Texas would result in a 6% ($10–$12 million per year) total *loss* to the program, along with $2.5 million per year in increased audit costs. Also, future customary charges would be pushed higher than the average 9% annual increases as drug manufacturers "cost shift" the losses from Medicaid to the private paying customer.
2. Since the bill's savings estimates from rebates are unlikely to be realized, Texas' open—and broad—formulary will have to be restricted in order to generate any savings. Extensive physician overrides, which are likely with any restricted formulary that permits them, would negate the majority of such savings.
3. To be allowed to continue its current system, the Texas Medicaid program would have to achieve approximately 15% savings in drug product cost over what it currently pays. Texas has already implemented "estimated acquisition cost" (EAC) drug pricing policies, so our state is placed at a substantial disadvantage over states that have continued to pay average wholesale price" (AWP) for drugs. For example, on a $10 AWP drug product, a state such as Arkansas need only negotiate on $8.50 real drug product cost (after rebate) to comply with the law, whereas Texas—where EAC policies mandate payment close to the pharmacists' actual cost of approximately $8.70 for the same drug—would have to negotiate a real price, after rebate, of $7.40 in order to be in compliance.
4. A stated objective of S. 2605 is to increase pharmacists' fees. As Dr. Kelley noted, S. 2605 can best be described as a reimbursement system that would "rob Peter to overpay Paul." Incidentally, pharmacy organizations are about the only public support Senator Pryor has for S. 2605, which is not surprising.

Let me reemphasize a point made by Dr. Kelley: Texas' highly successful system of reimbursement to pharmacies, which has been developed over the past 5 years, evolved in a climate of State/Federal partnership and program flexibility. Our system has resulted in a broad, stable provider population and excellent access to services. There seems to be little logic in removing all state flexibility in pharmacy reimbursement, which will negate established program savings. Savings attributable to drug rebate programs should be *in addition to* current program savings rather than instead of them. States should retain the flexibility to work with all the participants in the prescription market place to capture all potential savings from Medicaid programs.

STATEMENT OF HON. NANCY MCDONALD, TEXAS STATE LEGISLATURE

As a state legislator, registered nurse and member of the House Committee on Public Health, I am generally supportive of any and all attempts to contain health care costs. Approximately 16 percent of Texans lack basic health care coverage; as costs continue to escalate, decent medical care is placed farther from their reach.

However, I am vehemently opposed to S. 2605 because it seriously imperils the lives of low-income persons in the name of potential cost-savings. By requiring pharmacists to dispense the cheapest drug available within a therapeutic classification, S. 2605 fails to account for the variety of individual responses to various drugs. By freeing the pharmacist from any liability for these medical decisions, the bill further devalues the lives of low-income persons who receive Medicaid. In effect, under S. 2605, the very lives of many Medicaid recipients would be subject to a cost-benefit analysis that is pre-programmed to value prices over persons.

S. 2605 singles out low-income, often minority, individuals. In addition, it may actually increase health care costs overall as patients who are denied appropriate drugs become sicker and require more acute and more expensive care. In Texas' case I am told, S. 2605 may complicate program administration, making it more inefficient.

As a member of Texas' Mexican-American Legislative Caucus, I share the strong objections to the bill that have been expressed by the Mexican-American political Association, the National Coalition of Hispanic Health and Human Services Organizations (COSSMHO) and the United States Hispanic Chamber of Commerce.

As COSSMHO states in its June 20 letter to Senator Lloyd Bentsen, "The Medicaid crisis will not be solved by an easy and quick fix; it requires a comprehensive, thoughtful and sober response. Quality of care must be protected for current Medicaid patients and access to physician-prescribed medication is certainly a part of that quality assurance."

I understand and support Senator David Pryor's attempt to contain costs in the Medicaid program. I appreciate his willingness to thoroughly consider these plans and to do so with the participation of all interested parties. Such a thorough approach, I am confident, will yield an effective compromise that will save money without sacrificing the program or the people served by it.

MICHIGAN SOCIETY OF HEMATOLOGY AND ONCOLOGY,
Ann Arbor, MI, September 6, 1990.

Senator DONALD RIEGLE, JR.,
105 Dirksen Office Bldg.,
Washington, DC.

Dear Senator Riegle: This Society, which represents one hundred oncologists and hematologists, wishes too go on record as opposing Senator David Pryor's bill S. 2605. This bill places restrictions on Medicaid patients medications.

We feel that all efforts to mandate that certain drugs or treatments be limited are not conducive to good medical practice. Legislative interference with medical treatment decisions places the physician in the untenable position of deciding based on cost rather than best judgement for their patients.

Please help to defeat this bill when it comes before your committee. Thank You.

Sincerely,

JOHN BURROWS, *President*

NARD,
Alenandria, VA, September 27, 1990.

Hon. DONALD W. RIEGLE, JR., *Chairman,*
Health for Families and the Uninsured,
Subcommittee of the Finance Committee,
Washington, DC.

Re: September 17, 1990 Hearing on Medicaid Pharmaceutical Payment Alternatives: S. 2605 and S. 3029

Dear Chairman Riegle: On behalf of independent pharmacists in the United States we are pleased to respond to your request for a statement to become a permanent part of the published record of the cited hearing.

Our members, owners of 40,000 independent pharmacies, where over 75,000 pharmacists dispense more than 70 percent of the nation's prescription drugs and provide nearly 85 percent of the Medicaid pharmaceutical services, have endorsed both S. 2605 and S. 3029. In response to your request we are submitting for the record our endorsements of the legislation, our testimony before the Health Subcommittee of the Energy and Commerce Committee on September 14, 1990, and the text, of our presentation, *Medicaid Equal Access to Prescription Drug Pricing,* to the annual convention of the Michigan Pharmaceutical Association on August 15, 1990.

We strongly support this long overdue effort to provide price equity for the Medicaid *outpatient* prescription drug program. The other major Medicaid components that purchase prescription drugs enjoy the benefit of their nonprofit status prices. In fact, most nonprofits, even those serving virtually no indigent persons presently, acquire prescription drugs at special prices.

It is ludicrous to characterize the prices available to the Veterans Administration as "nominal." Arguably there are so called "nominal" prices in our marketplace, for example, a product provided to a nonprofit such as Planned Parenthood for a penny when the retail price is a dollar, is arguably "nominal."

We do not oppose exempting "nominal" prices from the determination of the AMP, however, we strongly urge that there be no tax benefit associated with providing products to the "nominal" prices beyond the actual cost involved.

Based on the Veterans Administration testimony to the Senate Aging Committee, they purchase single source prescription drugs at an average discount of 41% or .59 cents on the dollar; and for innovator multi-source prescription drugs they obtain an average discount of 67% or .33 cents on the dollar. "Nominal" means in name only. These prices reflect significant discounts but are not "nominal." In fact most nonprofit pricing is in this range or lower (see, Prescription Drug Marketing Act of 1987, hearing before the Subcommittee on International Trade of the Committee on Finance on S. 368, June 15, 1987, at page 84 and 85).

Whether or not original decisions to provide such prices for the Veterans Administration were motivated by patriotism, in our view is not particularly relevant. What is relevant is that radical discounts for nonprofits permeate our marketplace and S. 2605 and S. 3029 enable the most deserving nonprofit equal access to nonprofit pricing for prescription drugs.

The benefit of price equity in any particular state can be significant. In Michigan for example, which accounts for 4.3% of the total United States Medicaid outpatient drug expenditure, a modest discount, in the 20% range would yield $25 million dollars annually; and a discount in the 40% range, consistent with the average price for single source products to the Veterans Administration, would yield $50 million dollars in annual rebates for the Michigan outpatient prescription drug program. Of course a requirement of best price would yield even more.

The Michigan program between 1984 and 1989 has grown from $86,882,000 to an expenditure of $156,349,000. During the same period the number of recipients has decreased from 764,048 to 748,498 and the percent of the total Medicaid expenditure in Michigan for this program has increased from 6.5% to 8%. The number of prescriptions provided under the Medicaid outpatient program now totals 10,837,699 in contrast to the 1984 total of 9,133,525. The average price per prescription in 1989, for the program, was $14.52, and in 1984 it was $9.02.

Like the rest of the country it appears that Michigan spends approximately 80% on the drug ingredient and the remainder on pharmacy payment. Nationally, the pharmacy payment per prescription has increased from $3.04 in 1982, to $3.32 in 1987 or about 9%; and the ingredient cost, in contrast, has increased 80% during this period from $6.13 to $11.07.

In spite of, or maybe because of, these cold hard facts, the Health Care Financing Administration (HCFA) has sought to control prescription drug price inflation by unfairly confiscating the discounts that pharmacists earn in their private relationships with wholesalers, and by reducing or limiting coverage for beneficiaries. We are pleased that HCFA now supports the "best price" approach reflected in S. 2605 and S. 3029. It's about time that HCFA acknowledges what any school kid could determine, namely, that unfairly cutting pharmacists reimbursement and creating second class coverage for Medicaid beneficiaries do not address the cause of inflation of prescription drugs in the outpatient Medicaid drug program.

We think it is important to stress that nothing in this legislation reduces the billions of dollars in subsidies for research and development in the National Institute of Health appropriations; that nothing in this legislation reduces current special R&D tax credits for pharmaceutical corporations; and that nothing in this legislation reduces patent monopoly designed to assure recoupment of R&D expenditures and provide financial rewards for innovators.

We support the full access to prescription drugs for recipients in the Medicaid program contemplated by S. 2605 and S. 3029. Likewise, we support the modest effort to begin to provide restitution for the unfair taking, initiated in the mid 80's by the Reagan Administration, of the discounts that our small businesses earn for business frugality in their relationship with private wholesalers. Similarly, we support the provisions establishing a moratorium on any further similar unfair anti-small business initiatives by HCFA; and look forward to statutory changes that will assure fair reimbursement for retail pharmacy, the most competitive sector in the health care marketplace.

Thank you for the opportunity to provide our views in the published record of the cited hearing.

Sincerely,

John M. Rector, Esq., *Vice President of Government Affairs & General Counsel*

Enclosures.

NARD,
September 20, 1990.

Hon. Henry A. Waxman, *Chairman,*
Health and the Environment Subcommittee,
of the Energy and Commerce Committee,
2415 Rayburn House Office Building,
Washington, DC.

Re: Hearing on September 14, 1990, Medicaid Budget Initiatives; Medicaid Equal Access to Prescription Drug Prices for Indigents

Dear Chairman Waxman: We certainly appreciated the opportunity to testify in support of the Wyden-Cooper legislation H.R. 5589. Enclosed is a copy of the testimony to be published in the record of the hearing, including complimentary and explanatory exhibits.

I was asked by both Congressman Bliley and Congressman Nielson to respond for the record and upon receipt of their actual questions I will expeditiously provide answers.

We believe the questions regarding comparisons of retail versus manufacturer price "discrimination" is very important. As Congressman Wyden noted in his September 12, 1990 remarks, the manufacturers percentage of difference between the highest price retailers pay and the lowest price Medicaid should pay, range from 16 percent to 93 percent for single source drugs, and from 88 percent to 5,000 percent for the multi-source drugs. Typical retail discounts for example, for senior citizens, are in the range of 5 percent to 10 percent. An equally, important comparison is the reality of retail pharmacy's average 3 percent net profit versus an average net profit for manufacturers of 24 percent.

Thank you again for the opportunity to express our support for equal access in pricing for prescription drugs for Medicaid as provided in the Wyden-Cooper legislation.

Please let us know what more we can do to be of assistance in helping to assure that H.R. 5589 is enacted.

Sincerely,

John M. Rector, Esq., *Vice President of Government Affairs & General Counsel*

Statement of John M. Rector Before the House Energy and Commerce Committee, Subcommittee on Health and the Environment, September 14, 1990

Mr. Chairman, Members of the Subcommittee: [1]

I am John M. Rector. I serve as Vice President of Government Affairs and General Counsel for the National Association of Retail Druggists.

The National Association of Retail Druggists (NARD) represents the owners of 40,000 independent pharmacies, where over 75,000 pharmacists dispense more than 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily and *provide nearly 85 percent of the Medicaid pharmaceutical services.* NARD has long been acknowledged as the sole advocate for this vital component of the free enterprise system.

NARD members are primarily family businesses. We have roots in America's communities. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness that has made our country great.

---

[1] Henry A. Waxman (D-CA), Chairman—MAJORITY: (12-D) Representatives Waxman, James A. Scheuer (NY), Ron Wyden (OR), Gerry Sikorski (MN), Jim Bates (CA), Terry L. Bruce (IL), J. Roy Rowland (GA), Edolphus Towns (NY), Cardiss Collins (IL), Mike Synar (OK), Ralph M. Hall (TX), Dennis E. Eckart (OH), Bill Richardson (NM). MINORITY: (8-R) Edward R. Madigan (IL), William E. Dannemeyer (CA), Bob Whitaker (KS), Thomas J. Tauke (IA), Thomas J. Bliley, Jr. (VA), Jack Fields (TX), Howard C. Nielson (UT), Michael Bilirakis (FL)

We appreciate the opportunity to appear before the Subcommittee to express our support for sound Medicaid budget initiatives. We are especially interested in equitable cost containment amendments that recognize the actual source of the escalating costs of the outpatient prescription drug program and that provide the program *equal access* to manufacturer prices now available generally to Medicaid and to other nonprofit entities, including those serving indigents. The scandalous reality is that although Medicaid serves exclusively indigent persons, Medicaid has been denied access to the prices available for other comparable programs and entities that receive the "best" price. Instead of a first class program with *equal access* to prices for comparable entities, we have first class prices and second class programs.

We have supported as our top legislative priority this year the "Pharmaceutical Access and Prudent Purchasing Act," S. 2605, introduced by Senator David Pryor, Chairman of the Senate Special Committee on Aging. Medicaid *equal access* to prescription drug prices for indigents is the centerpiece of S. 2605. The basic equity of this long overdue approach enjoys wide support among consumer groups and especially those interested in the wellbeing of Medicaid recipients. The bill also enjoys strong bipartisan cosponsorship. The cosponsors include Senators Kerrey, Lott, Breaux, Baucus, Jeffords, Burdick, Exon, Conrad, Johnston, Bumpers, Adams and Kohl. Senate Majority Leader Mitchell told our annual Legislative Conference on May 7, 1990 of his support for this legislation. Health and Human Services Secretary Sullivan informed Senator Harkin as Chairman of the Appropriations Subcommittee on the Labor, Health and Human Services, Education, and Related Agencies, earlier this year, that such legislation could help provide states the leverage they needed to obtain the lowest prices. The Merck Sharp and Dohme Corporation offered state Medicaid programs its best price and pledged to limit price increases to the CPI. In June, the White House agreed with Senator Pryor and his allies that manufacturer prices are an appropriate target for Medicaid cost containment to be addressed in the Budget Summit. And more recently, other major pharmaceutical corporations have offered best price approaches.

We have strongly supported the efforts of the Budget Summit to provide Medicaid with *equal access* to pricing. Our best intelligence leads us to conclude that virtually all states are eager to negotiate *equal access* pricing. Several states, in anticipation of Congressional action, have enacted their own enabling legislation.

One of the first bills signed by Virginia's Governor Douglas Wilder was a Medicaid *equal access* bill. Additionally, the Maryland legislature has formally petitioned both Houses of Congress to enact *equal access* for Medicaid.

No one in the hearing room this morning needs to be reminded, however, that there is another point of view. In his remarks to his Senate colleagues on July 25, 1990, "Drug Manufacturers: Making Profits on Backs of Poor," Chairman Pryor explained the activities of our opponents. In summary he characterized their approach as "untrue and insulting." Interestingly, the opponents have focused almost exclusively on what the proposal is not. Although at times their approach has been unpleasant, at best, we are heartened by their collective failure to pose one sound argument in opposition to the actual *equal access* provisions of the Senate legislation.

Principally, beyond personal attacks on Senator Pryor, they have focused attention on the so-called "or else" clause. This *eq* the sanction to assure that *equal access* pricing is made available for Medicaid. Therapeutic exchange was the "or else" in S. 2605; more recently, denial of access to the Medicaid outpatient prescription drug program is the "or else."

Recently, Health and Human Services Secretary Sullivan told the Senate Appropriations Committee in response to a question about what could be done administratively to encourage equal access for Medicaid, in part that " . . . we have been unable to assist the states in overcoming their major problem of the refusal of drug manufacturers to submit bids."

This legislation provides the essential incentive—the "carrot," "hammer," "stick," "sugar"—to assure that the program will not in the future be denied *equal access* to prescription drug pricing as it has been in the past and is presently. The "or else" could have been a loss of special tax credits. The point is that a sufficient incentive is required to assure equity for Medicaid.

Our opponents have miscast this legislative effort as one that would mandate the "cheapest" prescription drug. The truth is that it will encourage all prescription drugs to be made available at the "cheapest" or "best" price.

Our opponents have argued that the legislation will mandate second-class treatment. The truth is that price equity for Medicaid will help assure that Medicaid recipients will have even fuller access to prescription drugs.

Our opponents have argued that the legislation mandates the "or else" provisions. The truth is that, unless there is an industry-wide criminal conspiracy not to provide Medicaid *equal access,* no one could honorably suggest that the "or else" provisions are mandated.

Our opponents have argued that the savings would be insufficient. The truth is that price discrimination so permeates the prescription drug marketplace, and the price discrepancies are so radical when compared to other markets, that assuring Medicaid the "best" price will yield significant savings.

Our opponents have argued that an unnecessary, burdensome, costly new bureaucracy would be required. The truth is that existing marketplace mechanisms, long ago established to provide the best price for nonprofits generally, including those like Medicaid that serve exclusively indigent persons, are already available to deliver price equity for the *most eligible* "best price" customer: the Medicaid outpatient drug program.

Our opponents have disingenuously claimed that because retail pharmacy pays the "highest price" for prescription drugs Medicaid should pay the "highest price." The truth is that all consumers are entitled to *equal access* and that discrimination in the general marketplace against retail pharmacy hardly supports continued discrimination against the Medicaid outpatient drug program.

Today we are pleased to support the efforts by Congressmen Ron Wyden and Jim Cooper and others to provide Medicaid equal *access.* We endorse the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990." We also have endorsed the Senate companion bill, S. 3029, the "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990," introduced September 12, 1990 by Chairman Pryor. Market forces have led to the denial of *equal access* to fair pricing for the Medicaid outpatient drug program. The indigent persons eligible for this Medicaid benefit are entitled to full pharmaceutical services and products. These bills will help guarantee the Medicaid outpatient prescription drug program *equal access* to prices established by individual corporations for nonprofit entities, especially those, like Medicaid, that serve exclusively indigent persons. We have no trouble with the notion of "nominal" prices being excluded, so long has there is no tax subsidy beyond the actual cost involved.

Substantial savings in the $3.5 billion dollar outpatient prescription drug program are associated with even modest reductions in the prices available to Medicaid. The Health Care Financing Administration (HCFA) certainly could have achieved price equity for Medicaid through the regulatory process. However, the agency has declined to do so, choosing instead to reduce beneficiary coverage and cut pharmacy reimbursement. These initiatives have had virtually no effect on overall prescription drug prices, but they have contributed to the second class stature of the program. We have had price controls for pharmacists in the Medicaid program since the early 70's. One interesting development this summer is that our opponents surprisingly announced their support for these price controls, including the most recent unfair lowering of the price control ceiling. Since 1985, all HCFA efforts to ostensibly control prescription drug costs in the Medicaid outpatient program have either assaulted small businesses participating in Medicaid or limited Medicaid beneficiary coverage. It is no coincidence that the leaders of this Congressional effort to assure a first class program for Medicaid recipients are nationally recognized small business advocates. Senator Pryor recently received the Small Business Advocate award from the Small Business Legislative Council, Congressman Wyden chairs the Regulation, Business Opportunities, and Energy Subcommittee of the Small Business Committee, and Congressman Cooper is an active, key member of the Antitrust, Impact of Deregulation and Privatization subcommittee or the small Business Committee. They are familiar with our marketplace; they know that the special monopolistic forces in our market have denied *equal access* to Medicaid and many other purchasers entitled to price equity. Our members, like these Congressional advocates, know that neither HCFA approach addresses the true source of the escalating cost to Medicaid.

We support consumer and Medicaid recipients' efforts for legislation that provides the Medicaid outpatient drug program *equal access* to manufacturer drug prices now available to Medicaid generally and to other nonprofit entities. We don't know the total percent of Medicaid expenditures for prescription drugs. The outpatient program, which is exclusively for drugs, amounts to 7 percent of the Medicaid program. Each of the largest Medicaid components (ICF—30%, in-hospital—27%, and SNF—13%), however, purchase an undetermined but significant amount of prescription drugs. A wide range of prices have been established for the same product. Special drug prices are available to nonprofits. Such sales are exempt from price discrimination laws. *These prices are not based on economies of scale or whether the purchaser takes possession of the drugs.* The nonprofit price is the lowest price. For example, a nonprofit entity pays $5 for a patented prescription drug while retail pharmacists and Medicaid currently pay $32. In the extreme, nonprofit entities pay 1 cent while retailers and Medicaid pay a dollar. Our position is that Medicaid, as a pure nonprofit program serving 100% indigent persons, is entitled to the lowest nonprofit charity prices established by the manufacturers. As noted, these prices are not based on the volume purchased or other economies of scale, but, in fact, are based on the nonprofit status of the purchasing entity. Special contracts known in our marketplace as "own use" contracts are written for nonprofit sales, but the regular private drug distribution system is used to store and deliver the product.

These marketplace mechanisms are common, inexpensive, not burdensome, and readily available for implementation of *equal* access for Medicaid. In effect, under the legislation, a state Medicaid program will sign an "own use" contract and receive its "best price" rebates via a chargeback or other well-established mechanism, typically from a drug wholesaler. These business practices are in place in virtually every Congressional district in the country.

The multiple pricing levels for prescription drugs in the United States have been thoroughly documented by this Subcommittee and the Subcommittee on Oversight and Investigations. In our view, most of this pricing conduct is illegal.

A recent Supreme Court decision, *Texaco. Inc.* v. *Hasbrouck,* June 14, 1990, emphasizes that even traditional distinctions in prices between a wholesaler and retailer will be found illegal unless there is a significant value-added aspect to the functional behavior of the wholesaler. This decision serves to highlight the bogus nature of multitier pricing, which provides mail order, drug vendors, nursing homes, HMOs, hospitals, and many other for-profit pharmacies significant competitive advantages to the detriment of independent retail pharmacy and consumers.

It is our view that only true charities, such as Medicaid or those otherwise providing uncompensated care, are entitled to discriminatory prices. There is, as mentioned, special treatment in the law for price discrimination to nonprofits. The 1938 *Nonprofit Institutions Act* (c.283, 52 Stat 446, May 26, 1938) exempts nonprofit institutions and those selling to them or facilitating the delivery of such sales from the general antitrust sanction for selling at different prices so long as the products are not resold. (In 1988, Congress enacted the *Prescription Drug Marketing Act.* Public Law 100–293, developed by this Committee, which made such resales serious felonies.) There is disagreement about the scope of the 1938 Act, but all agree that true charities, those serving indigents such as Medicaid, are entitled to obtain the lowest or "best" price. A major organization representing the pharmaceutical industry, for example, told the Senate Special Committee on Aging last summer that "This Act embodies the strong public policy in favor of allowing sellers to provide products at lower prices to charity purchasers."

Thus, there is a special pharmaceutical marketplace for nonprofit entities. To the best of our knowledge, all manufacturers have established the lowest price for this marketplace. These prices are enjoyed by nonprofit entities including hospitals, HMOs, nursing homes, mail order pharmacies, and others that serve few, if any, indigent persons. Basic equity demands that Medicaid have access to this special class of trade. The Wyden-Cooper legislation provides this equity.

Additionally, we Support provisions in Chairman Pryor's "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990," S. 3029, drafted in response to the Budget Summit initiatives that will begin to restore the unfair cuts in pharmacy Medicaid reimbursement of recent years. This restitution is achieved by setting aside a modest 10% of the rebates associated with *equal access* for Medicaid. The moratorium we have been seeking on further assaults by HCFA on pharmacy reimbursement reform for pharmacy providers are also included in S. 3029.

Additionally, we support a set aside of a very modest portion of the rebates to underwrite the efforts of investigators and prosecutors to police and otherwise enforce the *equal access* program.

In summary, we support Medicaid *equal access*:

- to provide a fair deal for Medicaid and its beneficiaries.
- to stop second-class treatment.
- to focus cost containment on the source of Medicaid drug costs and save at least $2 billion over 5 years.
- to provide to the Medicaid outpatient drug program prices already widely available to other tax-supported and nonprofit programs.
- to limits administrative costs by using the time-tested private enterprise system in place today in every state and in every Congressional district.

In closing, we would like to reiterate our strong support for providing *equal access* to prescription drug pricing in the Medicaid budget initiatives being negotiated by the Budget Summit that will eventually be addressed by both the House of Representatives and the United States Senate.

In the next Congress we look forward to helping to establish significant Medicaid pharmacy reimbursement reform by law, and to making more progress in the broader campaign to guarantee *equal access* to prescription drug pricing throughout the private marketplace and for independent retail pharmacy customers in particular.

If I have been asked once, I have been asked a 1,000 times: Why is the pharmaceutical industry opposed to *equal access* pricing for Medicaid?! Certainly, it's not our responsibility to answer this question, but perhaps a May 10, 1990 *Washinaton Post* article, by Spencer Rich, entitled "Senator Seeks to Stem Rise in Medicaid Drug Costs," provides some insight to the answer. It read in part as follows:

> " . . . the Pryor plan is strongly opposed by the Pharmaceutical Manufacturers Association, which sees it as an *opening wedge to cut prices everywhere.* (emphasis added) 'If these misguided policies were adopted at the Federal level in Medicaid, you'd see a lot of attempts to move those policies into the private sector,' said the PMA president . . . "

In fact, when Senator Pryor introduced S. 2605, he said to his Senate colleagues, on May 10, 1990:

> "By now it may be obvious that while the drug companies don't want to negotiate drug prices with Medicaid programs, Medicaid isn't the issue. They are deathly afraid that the rest of the American public, those with workplace and retiree health plans, will be able to get the same deals by using the same negotiating strategy. Or in other words, they are afraid the idea will spread and catch on. Mr. President, I would like my colleagues to think about this for just a moment: when was the last time someone asked us to vote against an idea because it was so good it might catch on?"

We hope that they are right. We hope that it does catch on.

Ultimately, we support legislation to insure equal access for fair prices for retail pharmacy and consequently for the majority of American consumers who are presently victimized by multitier pricing. But for now and for the remainder of the 101st Congress, Second Session, our top priority is the enactment of *equal access* for Medicaid.

On behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to participate in the development of Medicaid budget initiatives in response to the Budget Summit.

SUMMARY OF MEDICAID ANTI-DISCRIMINATORY DRUG PRICE AND PATIENT BENEFIT RESTORATION ACT OF 1990 (SENATOR DAVID PRYOR D–ARK)

CONDITIONS OF COVERAGE OF DRUG PRODUCTS UNDER MEDICAID

The legislation requires that in order to be placed on a Medicaid prescription drug formulary (the State's covered drug list) or to be covered by a state Medicaid program, a prescription drug manufacturer must provide the Medicaid program the same substantial discounts it is now giving to other purchasers of its medications. (Currently, many manufacturers are providing in excess of 40 to 60 percent discounts to hospitals, HMOs, the Department of Defense and the Department of Veterans Affairs for the very same drugs purchased by Medicaid) .

The required discounts, provided to the States through a rebate system, apply to the single source and innovator multiple source drug products of the brand name drug companies.

If a manufacturer fails to give such discounts to any one State, no Federal matching dollars will be provided for that drug manufacturer's medication in all States. (This provision has the effect of denying manufacturers' access to the Medicaid market, which usually constitutes 10-15% of the average manufacturer's business; such an approach should protect smaller States from being denied access to discounts).

DEFINITION OF ACCEPTABLE MEDICAID REBATES

The value of the acceptable discount for single source and innovator multiple source drugs is equal to the difference between the price that manufacturers charge wholesalers to buy their products (known as the Average Manufacturers' Price, or AMP) and the "best price" that the manufacturer offers to any other purchaser of these drug products (AMP minus best price = value of the rebate). The AMP is the price that the manufacturer charges pharmaceutical wholesalers to buy their products.

To ensure that Medicaid continues to receive the lowest price in the marketplace, the "best price" is defined as the lower of the "best price" in the marketplace during the calendar quarter in which the drug is dispensed or the "best price" in place in the market as of September 1, 1990, indexed to the consumer price index (CPI). The definition of "best price" excludes those prices that are merely nominal in amount that manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood.

The indexing mechanism is absolutely necessary because cost estimators such as CBO and OMB, are highly unlikely to project significant savings for any proposal that would allow manufacturers to eliminate or significantly reduce current discounts.

In addition, when a voluntary manufacturer rebate approach was tried for cans of infant formula provided by the WIC program, the manufacturers tried to eliminate the rebates by significantly raising their "best prices."

The total aggregate value of the discount payment collected by each state Medicaid agency from each drug manufacturer can be no less than 10% of total state expenditures under Medicaid that are attributable to ingredient costs (AMPs) for drug products sold by the manufacturer. Manufacturers who are now discounting at drugs at significantly high levels (some are discounting in excess of 60%) have argued that freezing such discounts would leave them no alternative but to not participate in Medicaid program. To counter any drug manufacturer argument that it cannot afford to participate in Medicaid, the total amount that the manufacturer will be required to rebate will be capped at 25% of the total state expenditures attributable to their drugs.

The rebates are paid quarterly by the manufacturer to each state Medicaid plan. The agreements are for one-year and are automatically renewable unless terminated by the manufacturer or the Secretary. The Secretary can bar a manufacturer from participating in the Medicaid program for one year if an agreement is terminated with any state.

For non-innovator multiple source drug products (generics), the manufacturer is required to rebate a flat 10% of the total aggregate expenditures for all that manufacturers' drug products as a condition of Medicaid coverage.

QUALITY OF CARE IMPROVEMENTS FOR MEDICAID PATIENTS

1. *Access to Prescription Drugs Expanded:* The bill will significantly expand Medicaid beneficiary access to a wide range of FDA-approved prescription drug products and biologicals. In addition, physicians will be assured that they can prescribe these products for "off-label" indications if such use is supported by medical compendia.

To insure that Medicaid beneficiaries have access to all FDA-approved drug products, those drug products not subject to the discount (and hence not on the state formulary) can still be obtained if the physician obtains prior approval from the state Medicaid program. The bill insures that the final control over the drug product selected for the patient is retained with the patient's physician. There are no provisions in this bill for therapeutic substitution or therapeutic interchange of drug products by pharmacists.

2. *Reform of Prior approval Programs:* To make prior approval programs more responsive to physicians needs, states can only operate these programs if they meet certain minimal standards: they must be available to physicians 24 hours/day, 7 days a week, and provide a response to the physician's request which must be received by the inquiring physician immediately.

3. *Drug Utilization Review:* The bill establishes a comprehensive system of drug use review (DUR) that encourages pharmacists to counsel patients on the proper use of their medications and requires state medical assistance programs to implement a program to avert inappropriate patterns of prescribing and dispensing of drug products.

NO COVERAGE FOR DRUG PRODUCTS SOLD ONLY WITH EXCLUSIVE PATIENT MONITORING SERVICES: The bill does not require the state medical assistance plan to cover those drug products of manufacturers which require that, a condition of sale of the product, the manufacturer be compensated for associated tests or services associated with the use of the product which are provided exclusively by the manufacturer or its designee. Serious questions have been raised by the medical community about the appropriateness of such a requirement. Thus, the state does not have to cover a drug of this type if it is included among the products of a manufacturer that has entered into an acceptable rebate agreement. An example of this is Clozaril, the antischisophrenic that can only be obtained if exclusive patient monitoring services are purchased from the manufacturer.

MEDICAID PRESCRIPTION CLAIMS PROCESSING: State medical assistance plans are given incentives to develop and implement a cost-saving on-line pharmacy-based electronic system to process Medicaid prescription drug claims. The encouragement given to the states is in the form of a 90/10 FFP match.

RESTORATION FOR PHARMACY REIMBURSEMENT CUTS: For approximately three years after enactment, some of the cuts that have been made in pharmacy reimbursement over the past decade are restored by setting aside 10% of the rebates received each year by the state for this purpose. Pharmacies will receive a fixed rebate for each prescription that they dispense to Medicaid beneficiaries in an annual lump-sum payment.

REFORMATION OF MEDICAID PHARMACY REIMBURSEMENT SYSTEM: The bill would effect reforms in the current pharmacy reimbursement system. After the three year pharmacy restoration expires (as described above), states would be required to update pharmacy dispensing fees each year based on the results of an annual study. In addition, the bill places a two-year moratorium on any further reduction in drug product cost reimbursement for brand-name drug products and instructs the Secretary to develop a "look behind" program to provide better enforcement of the HCFA "brand medically necessary" requirement designed to promote generic substitution. establishment of an 13-member Prescription Drug Policy Review Commission to advise Federal and state policy makers on policy and financing matters relating to publicly-funded prescription drug benefit programs, including Medicaid and Medicare.

DEMONSTRATION PROJECTS: Provides for a demonstration project on the effectiveness of on-line prospective drug utilization review in pharmacists' fulfilling patient counseling requirements and a demonstration project on the cost-effectiveness of pharmacists' providing cognitive services to patients.

STUDIES: Requires that a study be done on the scientific and clinical foundation for the concept of therapeutic interchangeability among drug products.

Further information about the bill can be obtained from Chris Jennings or John Coster at the staff of the Senate Aging Committee, X–45364.

Summary of the Wyden/Cooper Medicaid Prescription Drug Fair Access and Pricing Act of 1990

I. CONDITIONS OF COVERAGE OF DRUG PRODUCTS UNDER MEDICAID

The Federal Government would no longer provide Medicaid matching dollars for a manufacturer's pharmaceutical products if the manufacturer does not have a discount agreement in effect with the secretary of Health and Human Services.

Each manufacturer which enters into a discount agreement with the Secretary shall be assured open access to all states' Medicaid drug formularies. Discount agreements would apply to single source and innovator multiple source drug products.

II. DISCOUNT AGREEMENT REQUIREMENTS

Discount agreements must equal the difference between the price that manufacturer's charge wholesalers for a product (known as the Average Manufacturers' Price, or AMP) and the "best price" that the manufacturer offers to any other purchaser of a drug (i.e., AMP minus best price = value of the discount agreement).

To ensure that Medicaid continues to receive the "best price" in future years, the "best price" is defined as the lower of the best price during the calendar quarter in which the drug is dispensed *or* the best price offered to other purchasers as of September 1, 1990, indexed annually to the Consumer Price Index (CPI). "Best price" does not include those prices which are merely nominal in amount (for example, the sale of birth control pills for a penny a pack to Planned Parenthood).

The indexing provision of the bill prevents drug manufacturers from increasing their costs over time to offset the discount requirements. Without an index, manufacturers would be able to raise prices by a commensurate amount of the discount, thereby eliminating or severely reducing the value of the "best price" concept. For example, under the voluntary rebate arrangements of the Women, Infants, and Children (WIC) program, infant formula manufacturers tried to eliminate the rebates by significantly raising their best prices."

The total aggregate value of the discount arrangement for each manufacturer cannot be less than 10 percent of total state expenditures attributable to the AMPs for the manufacturer's drugs. To ease the transition into best prices, a discount ceiling for each manufacturer of 25 percent would be established for the first two years, increasing to 50 percent for years three and four, and achieving full "best prices" for the Medicaid program by year five.

Rebates will be calculated and paid to states on a quarterly basis. Discount agreements will be effective for a minimum of one-year and are automatically renewable unless terminated by the manufacturer or the Secretary. If an agreement is terminated, the Secretary can bar a manufacturer from participating in the Medicaid program for one year.

III. NON-INNOVATOR MULTIPLE SOURCE DRUG (GENERIC) DISCOUNTS

Generic drugs will be required to offer discount arrangements to the Federal Government equal to at least 10 percent of the total aggregate expenditures for a the manufacturer's drugs. The Federal government will deny matching funds for the products of any generic manufacturer which does not have a discount agreement in effect with the Secretary.

IV. EXPANSION OF ACCESS TO PRESCRIPTION DRUGS

i. Open Formularies

The legislation will significantly expand access to a wide range of FDA-approved prescription drug products and biologicals. In states which use restrictive formularies, beneficiaries will be given new access to a significant number of prescription drugs for which payment had been prohibited.

An exception to the open formulary rule will be allowed for drug products for which the manufacturer requires compensation for tests or services associated with the use of the drug product. For example, Clozaril, an antischizophrenic drug, is currently only available if purchasers also agree to pay for expensive patient monitoring services provided by entities under exclusive contract with the manufacturer. Serious questions have been raised by the medical community about the appropriateness of such a arrangements..

ii. Physician's Right to Prescribe

The bill ensures that the final control over the drug product selected for the patient is the sole responsibility of the patient's physician. There are no provisions in this bill for therapeutic substitution of drug products by pharmacists.

iii. Prior Approval Reforms

The legislation sets in place basic standards for state prior approval programs. These standards will make prior approval programs more responsive to physicians' and patients' needs by requiring that such programs provide a response to physicians 24 hours/day, 7 days a week, and provide for an immediate response to the physician's request.

iv. Drug Use Review

A comprehensive system of retrospective and prospective drug use review will be established to prevent inappropriate prescribing and dispensing, and to encourage pharmacists to counsel patients on the proper use of their medications.

PRESENTATION OF JOHN M. RECTOR, ESQ., VICE PRESIDENT OF GOVERNMENT AFFAIRS AND GENERAL COUNSEL, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS BEFORE THE 107TH ANNUAL CONVENTION OF MICHIGAN PHARMACISTS ASSOCIATION MEDICAID EQUAL ACCESS TO PRESCRIPTION DRUG PRICING TRAVERSE CITY, MICHIGAN, AUGUST 15, 1990

We are certainly pleased to participate in your 107th annual convention. At the outset I would like to acknowledge President Robert Hamilton and Chairman William Patterson. A special thanks to Larry Wagenknecht and Lou Sesti for their courtesy and assistance in arranging today's session.

Since 1898, the National Association of Retail Druggists (NARD), has represented the professional and proprietary interests of independent pharmacists in the United States. The NARD has had a long credible tradition of involvement in the legislative and political processes. I have been with NARD for 10 years, responsible for the legal, political and legislative issues. I am personally very proud to be part of the NARD tradition.

It is not my task this morning to address pharmacy education issues, but as your counsel has probably told you, law students learn a good deal about the NARD. Especially in courses in anti-trust and other legislative initiatives designed to curb anti-competitive conduct, harmful to the consumer generally, and to small businesses, including independent retail pharmacy. Occasionally, I have had the impression that law students curiously have been exposed more to the NARD than pharmacy students. Whether the educational program is 5 years or 6 years, and certainly the NARD concurs with the overwhelming views recently expressed by your membership, that a 5 year program is preferable, a graduate should know the basics. At any time, but especially in these times, it seems it is essential that pharmacy education include more exposure to public policy matters but especially political and legislative issues that are crucial to pharmacy in every setting where the profession is practiced.

On a personal note, for a variety of reasons, I have generally very positive associations with your state of Michigan. My spouse, also a Washington lobbyist and former Senate Judiciary staff director and her family are from Michigan. Your distinguished former Senator Phil Hart set the standard for ethical and substantive pursuits in the United States Senate. As a chief counsel and staff director for the Senate Judiciary Committee, I worked closely with him through the 70's, until his untimely death. The recent Wyden legislation, to prohibit doctor merchants from a double monopoly by making illegal the selling of prescriptions, was modeled on Senator Hart's 1971 bill.

In a similar vein, I had a even longer association with former Congressman Jim O'Hara, who was a member of the delegation from Michigan for 16 years. In fact, as a young lawyer I thought of him as a mentor. In more recent years, since 1981, Jim was a distinguished partner in Washington, D.C.'s premier legislative firm, Patton and Boggs. Jim O'Hara and I worked together on behalf of several NARD legislative priorities. Our Legislative Defense Fund lobbying film features him in mock Congressional visits on today's subject: discriminatory pricing. It is dedicated to his memory.

Most of you are aware that Congressman John Dingell from Dearborn, is very influential. As Chairman of the Energy and Commerce Committee, he is responsible for nearly one half of the legislation in the House of Representatives. In our area of interests and also many others, to say that he is very influential would qualify as the understatement of the year. On many issues he has been of great assistance to independent retail pharmacy, for example, he was the principal author of the *Prescription Drug Marketing Act.* On today's subject of discriminatory pricing, more than 20 years ago as a member of the Small Business Committee, he held extensive hearings on multitier pricing in the pharmaceutical industry. It is certainly an honor to be on the program this morning, with Mike Barrett, the chief counsel and staff director of the Oversight Subcommittee, also chaired by Congressman Dingell.

Congressman Dingell and Senator Riegle are key players in the eventual outcome of today's topic: Medicaid Equal Access to Fair Prescription Drug Pricing. In fact the Energy and Commerce Health Subcommittee will hold a hearing on the Pryor legislation a month from yesterday; and the Senate Finance Subcommittee Health for Families and the Uninsured, chaired by Senator Riegle will hold a similar hearing a month from this Thursday. Senator Riegle is also a key member of the Budget Committee. Thus a member of the Michigan Pharmacy Association you have an unique opportunity to impact the campaign for equal access to fair pricing for Medicaid.

I noted your theme, "New Horizons in Pharmacy in the Year 2000." The NARD Executive Committee in 1985, targeted the elimination of discriminatory pricing by the year 2000. In our view most of retail pharmacy, especially independent pharmacy's problems are spawned and sustained by discriminatory pricing. In effect all roads lead to discriminatory pricing, whether it be mail order pharmacy, confiscation of earned discounts, the non-profit competitor, the dispensing physician, managed care with closed contracts, and on and on and on. Discriminatory pricing is their life blood.

The Task Force on Discriminatory Pricing Legislation comprise of NARD, APhA, NACDS and the Pharmacy Freedom Fund, adopted the theme of equal access to address the problem. Equal access for all to prices under the same terms. It is no coincidence that the success of the equal access campaign is occurring after a series of Congressional investigations in the 1980's that increasingly focused on manufacturer pricing practices: the drug diversion investigation conducted by Congressmen Dingell and Wyden, the Waxman hearings in 1985 and 1987 on drug pricing, the mail order investigation by Senators Sasser and Mitchell, the debate about the catastrophic drug benefit and the obvious difference in a acquisition costs between the inpatient program and the proposed outpatient program, Senator Pryor's historical hearing in 1989; and more recently the Clorazil controversy with it's pricing at $30 a week in Great Britain and $172 a week in the United States.

Regarding Clorazil, it appears that discriminatory pricing yields discriminatory distribution. We have received reports that this anti-pharmacy marketing is a stockinghorse for dozens of other products. Consequently, all but one, ASCAP, of the members of the Joint Commission of Pharmacy Practitioners (JCPP), have helped coordinated a national campaign to prevent this anti-competitive marketing. In a recent issue of *Pharmaceutical Executive,* Mr. Link of Sandoz noted the negative reaction by pharmacists as follows, "Their umbrella organization the Joint Commission of Pharmacy Practitioners (JCPP), has even sent a strong letter to protest to Jacques Rejeange CEO of Sandoz USA. JCPP believes the Clorazil system unjustifiably takes pharmacists out of the dispensing loop. It sees no reason for making Clorazil an exception to the rule of pharmacy dispensing as practiced for virtually all other medicines. JCPP also criticizes Sandoz for denying patients the opportunity for pharmacist counseling."

All of these and others have heightened the interest of Congress in the basic lack of equity in the prescription drug marketplace. There are Congressional efforts aimed at achieving equity in the private marketplace and there is an effort to provide Medicaid pricing equity, which I will address today.

We have provided several documents, or handouts, on the *Pharmaceutical Access and Prudent Purchasing Act,* (PAPPA), S. 2605, including the NARD July Journal coverage of our 23rd Annual Legislative Conference; a recent letter from Senator Pryor to all state pharmacy associations; two charts illustrating the national experience of retailers in Medicaid and the NARD equal access position as published in the April Roll Call, the inside newspaper for Capitol Hill.

We are late in the 2nd session of the 101st Congress. Congress is scheduled to adjourn in early October. The rebate provisions of the Pryor legislation are very likely to be enacted as part of the Budget Summit legislation that you have been hearing and reading about.

In each Congress approximately 10,000 bills are introduced. This Congress is not an exception, more than 8,500 bills and another nearly 1,000 resolutions have been introduced. In someones mind each of these has merit. It's important to note, however, that the President signs each Congress, in the neighborhood of 300 to 400 bills into law. What moves a bill from the crowd of 10,000 to the short list signed by your President? I can guarantee you, it's not merit alone. I hasten to add, however, that the measure must have merit, but politics plays a major role in determining the short list. Today's subject is likely to be on the short list.

Today's subject is far more simple than our opponents have made it seem. Of course, any time there are differences of opinions involving billions of dollars there will be differences in determining the actual facts.

I am reminded of a comment from former President Johnson, that highlights the difference between a pharmacist and a lawyer. LBJ said, "A town that can not support one lawyer, can always support two." On today's subject 100's of lawyers and others that participate in the legislative process are hard at work.

The good news is that we are winning. The bad news is that, however, not all of us know it. Of course that is understandable. It's the mission of our opponents to confuse, sidetrack, make complex, and delay.

Last Tuesday's Wall Street Journal, featured an article that captured this in it's opening, "Pharmaceutical companies are working furiously to head off a revolt against drug prices spearheaded by their biggest customer: the U.S. government."

At times the debate, or more accurately, the effort to avoid debate has been especially tough and down right nasty.

> The opponents attacked Pryor as a racist; the opponents have attacked pharmacy as irrelevant; the opponents have attacked fair pharmacy reimbursement as inflationary; and the opponents have attacked consumers by tempting to scare them into believing that fair pricing equates to second class medicine.

To a degree some of what they have done has worked. Some of the hundreds of calls we have received reflect the minimal success that they are having. In the main, we are winning and most concur with Senator Pryor's July 25, 1990 presentation to the United States Senate, where he characterized the opponents attacks as "untruthful and disgusting."

The attack on pharmacists and pharmacy could easily be characterized as vicious. "Insensitive" would put it in it's best light. It reminds me of a paraphrase of W.C. Fields comment about children, "I like pharmacists if they are properly cooked."

I don't have the time this morning nor the inclination to reiterate all the gory details, suffice it to say it's a tough often bitter battle, where there is no middle of the road. As the current Secretary of Agriculture in Texas, Mr. Hightower, has observed, "There is nothing in the middle of the road except yellow stripes and dead armadillos."

At this point I would like to review some of the basic facts about our market and facts about PAPPA. In light of the apparent limited success of our opponents, I will spend a little time later focusing on what *PAPPA is not.* But first, facts about our market.

The prescription drug marketplace in the United States is *unique, peculiar, different, unlike* most retail marketplaces. There are special monopolistic practices with a high abuse potential. Patents are granted to inventors to recoup research and development investments and physicians have a monopoly on prescribing. As a consequence, our market is not consumer driven. In addition to these unique aspects the one characteristic that distinguishes our market from all others is multitier pricing, with it's radical levels of price discrimination.

I can vividly recall in the opening hearings on Medicare Catastrophic drug benefit. The National Counsel of Senior Citizens' witness urged Congress to determine how it is that a prescription drug costs one consumer $18.25 and the same drug costs another consumer .73 cents? Senator Pryor, in June of 1989 opened his investigation on equal access by featuring a well known prescription drug available at 3 prices: $5.00, to the nonprofit entity, $8.00 to the Veterans Administration, and $32 to, you guessed it, retail pharmacy.

The nonprofit prices are especially relevant to today's subject, after all Medicaid by definition is a program for indigents, in fact 100% of the recipients are indigents. The prices available to nonprofits are not based on economies of scale, such as volume purchased, but are available under the *Nonprofit Institutions Act,* as interpreted by cases such at *Portland Retail Druggists Association* v. *Abbott Labs, et. al.* You are familiar with "own use" contracts available to nonprofit hospitals, HMOs, nursing homes, and even mail order pharmacies. Market forces have denied Medicaid their own use contracts. This is what PAPPA is about. Other programs in Medicaid obtain special prices for prescription drugs: the ICF's which accounts for 30% of Medicaid, the inpatient hospital program which accounts for 27%, and SNF's which accounts for 13% each obtain special prices; but not the outpatient program which accounts for 6 to 7 percent of Medicaid expenditures.

Much has been said in recent months about the prices available to the Veterans Administration. Based on the Veterans Administration testimony to the Senate Aging Committee, they purchase single source prescription drugs at an average discount of 41% or .59 cents on the dollar; and for innovator multi-source prescription drugs they obtain an average discount of 67% or .33 cents on the dollar.

The PAPPA begins to require the availability of such prices for the Medicaid outpatient drug program. Voluntary efforts in the past decade have uniformly failed to produce results. Those setting the nonprofit prices refuse to sell to the Medicaid outpatient drug program just as they refuse to sell to independent buying groups.

What PAPPA says is, equal access for Medicaid "or else." This is the sanction to assure that equal access pricing is made available for Medicaid. Therapeutic exchange was the "or else" in S. 2605; more recently, denial of access to the Medicaid outpatient prescription drug program is the "or else." Recently, Health and Human Services Secretary Sullivan told the Senate Appropriations HHS Subcommittee Chairman Harkin, in response to a question about what could be done administratively to encourage equal access for Medicaid, in part that " . . . we have been unable to assist the states in overcoming their major problem of the refusal of drug manufacturers to submit bids."

This legislation provides the essential incentive—the "carrot," "hammer," "stick," "sugar"—to assure that the program will not in the future be denied equal access to prescription drug pricing as it has been in the past and is presently. The "or else" could have been a loss of special tax credits. The point is that a sufficient incentive is required to assure equity for Medicaid.

Some who have been confused about the object of PAPPA have wondered out loud, what is in this for pharmacy? At a bare minimum the pressure for future cuts in pharmacy reimbursement will be alleviated, more on this later.

Incidentally, one notable "wolverine" that I had not mentioned was Caroline Davis, who headed the HCFA for much of President Reagan's two terms. She was a principal architect of the campaign to confiscate the discounts earned by retail pharmacy. Certainly, she and others could have attempted to provide equal access for Medicaid and fair prices but instead they unfairly cut pharmacy reimbursement and cut back on benefit coverage. She's one that we wished had stayed in Ann Arbor.

What is involved with the PAPPA rebates? If Medicaid obtains a 20% reduction, $600 million dollars each year is involved. Enough to fund the entire budget for one year of the FDA, or as we recently learned, to underwrite the United States effort in the Gulf for 2 months. If Medicaid obtained prices comparable to the Veterans Administration prices, $1.2 billion dollars is involved. Michigan's share of that $1.2 billion is 4.3% or nearly $52 million dollars. In the budget summit, and very likely to be included in legislation introduced in September will be a set aside of 10% of the rebate for retail pharmacy. The notion here is restitution to begin to restore the unfair cuts in pharmacy reimbursement in the last 6 years.

These are significant numbers. The Michigan program between 1984 and 1989 has grown from $86,882,000 to an expenditure of $156,349,000. During the same period the number of recipients has decreased from 764,048 to 748,498 and the percent of the total Medicaid expenditure in Michigan for this program has increased from 6.5% to 8%. That $50 million would off set nearly ⅓ of the cost of the program.

Incidentally, there have been some rumblings that the chains may not want a share of the 10% set aside. If that turns out to be the case we certainly have no objection to independents preceiving the full set aside. Nation wide independents presently provide 85% of the Medicaid prescriptions. Such a development could have interesting consequences. Many distinguish between independents and chains based on an arbitrary number of pharmacies, for example, four or more, rather than criteria that accurately delineates an independent from a chain. If the set aside was available only to non-chains, I think we would achieve a suitable definition that reflects the actual numbers of independent and chain pharmacies.

Like discriminatory pricing, generally this Medicaid equal access issue is a consumer issue, it is not a pharmacy vs. manufacturer issue. The NARD, APhA, NACDS support the legislation as "fair, wise, and workable." The ASHP, and the ASCAP mistakenly seem to think that providing fair prices for Medicaid outpatient program will threaten the special prices they now receive. In any case, it is certainly an ironic blessing in disguise that these two organizations have only recently decided to become active in the legislative and political processes.

PAPPA enjoys wide bipartisan support in the United States Senate. Most major consumer groups support PAPPA. So what is all the flap about?

If we have been asked once we have been asked a thousand times why manufacturers oppose poverty prices for the Federal poverty program? Certainly it's not our responsibility to answer this question, but perhaps a May 10, 1990 Washington Post article, by Spencer Rich, entitled "Senator Seeks to Stem Rise in Medicaid Drug Costs," provides some insight to the answer. It reads in part as follows:

> " . . . the Pryor plan is strongly opposed by the Pharmaceutical Manufacturers Association, which sees it as an *opening wedge to cut prices everywhere.* (emphasis added) 'If these misguided policies were adopted at the Federal level in Medicaid, you'd see a lot of attempts to move those policies into the private sector,' said the PMA president . . . "

In fact, when Senator Pryor introduced S. 2605, he said to his Senate colleagues, on May 10, 1990:

> "By now it may be obvious that while the drug companies don't want to negotiate drug prices with Medicaid programs, Medicaid isn't the issue. They are deathly afraid that the rest of the American public, those with workplace and retiree health plans, will be able to get the same deals by using the same negotiating strategy. Or in other words, they are afraid the idea will spread and catch on. Mr. President, I would like my colleagues to think about this for just a moment: when was the last time someone asked us to against an idea because it was so good it might catch on?"

We hope they are right. This is a main goal of independent pharmacy. We hope that it does catch on.

I had mentioned earlier the importance of what PAPPA *is not.*

PAPPA is not therapeutic substitution / it is negotiated nonprofit prices.

PAPPA is not a tax / it is price equity.

PAPPA is not second class medicine / it expands recipient access.

PAPPA is not expensive overhead / it uses existing business practices.

PAPPA prices are not based on volume or depot shipment / it is based on the nonprofit status of Medicaid.

PAPPA pharmacy reimbursement is not inflationary / it restores unfair cuts and provides a sound marketplace approach.

And lastly, PAPPA and pricing is a subject that can be discussed / the anti-trust laws under the Noerr Pennington Doctrine exempts legislative inquiries and related legislation and bonafide efforts related to both to both from sanctions.

As I mentioned, both Chairman Dingell and Senator Riegle will play key roles in the outcome in September. Interestingly two weeks ago both of these influential members of the Michigan delegation addressed the House and Senate respectively on the 25th anniversary of Medicare and Medicaid.

Congressman Dingell on July 30, 1990 spoke of legislation introduced in 1943 (my birth year folks, August 15, 1943) by his father who represented Dearborn and Senators Robert Wagner of New York, and Jan Murray of Montana that proposed a National Health Insurance plan. Congressman Dingell noted that his father did not live to see Medicaid and Medicare developed and be enacted, but many of the provisions of the Wagner/Murray/Dingell bill were included in these programs. Incidentally, in each Congress, in fact all 18, Congressman John Dingell has introduced H.R. 16 containing the other provisions of the legislation introduced in 1943.

He told the House that he supports " . . . equal access to quality health care for all." Importantly, Congressman Dingell said, *"We must remember that dreams do not come easily to fruition, neither then or now."*

Discriminatory pricing must and will end. We are on the right track but as Will Rogers once said, "Even if you are on the right track if you sit down you will get run over."

We have a lot of work to do on PAPPA which is a first good step. We are winning. In reviewing this subject I am reminded of a comment by Mo Udall of Arizona, a highly respected and equally humorous Member of Congress. He has observed that to address some subjects, "A kind word and a gun rather than a kind work alone, comes highly recommended." Equal access is such a subject.

Good luck with your Michigan delegation and thank you again for the opportunity to be with you this morning.

MICHIGAN PHARMACISTS ASSOCIATION,
Lansing, MI, August 17, 1990.

JOHN RECTOR, *Vice President of Governmental Affairs & General Counsel,*
National Association of Retail Druggists,
205 Daingerfield Road,
Alexandria, VA 22314

Dear John: Thank you again for your participation in the 107th MPA Annual Convention of the Michigan Pharmacists Association.

Your message was forthright and factual . . . it is an issue about which every community pharmacist should indeed be concerned and should applaud the efforts of NARD in seeking the resolve to discriminatory pricing.

While it may not be the words which the pharmaceutical industry wants to hear, it nevertheless must be the unending goal of pharmacy to bring it to the forefront . . . since, as you said, it is indeed so often the "root of all (our) evils."

It is also a story which some pharmacists in hospital pharmacy practice and those associated with HM0s may find to be a mixed message; but, nevertheless, the astute professional realizes that wrong is wrong and its remedy must be pursued by the aggrieved.

Pharmacy must, in my opinion, continue to pursue the principle of one price for all, with only volume being the acceptable variable. This is why I feel the so-called "voluntary rebates are a sham . . . bringing with it unacceptable provisions as "no formulary" and "no therapeutic substitution." These provisions are a matter of public policy and professional policy which should not be determined by pharmaceutical manufacturers in "special deals" with Medicaid agencies.

Sincerely,

LOUIS M. SESTI, *Chief Executive Officer*

The National Association of RETAIL DRUGGISTS

NATIONAL HEADQUARTERS
205 DAINGERFIELD ROAD
ALEXANDRIA, VIRGINIA 22314
(703) 683-8200

WASHINGTON BULLETIN

CONTACT:
John M. Rector, Esq.
Vice President of
Government Affairs
& General Counsel

May 16, 1990

HHS SECRETARY SULLIVAN TELLS SENATOR HARKIN MAY SUPPORT PRYOR LIKE LEGISLATION

We have been working closely with Senator Tom Harkin and his key legislative staff in a continuing effort to establish a more equitable Medicaid program for both pharmacy and beneficiaries. Senator Harkin, as Chairman of the Labor, Health and Human Services, Education, Subcommittee of the Senate Appropriations Committee recently submitted a series of questions to HHS Secretary Sullivan. They deal with two categories:

1. Medicaid drug reimbursement and a possible moratorium on the current effort by the Bush Administration to force states to confiscation retail pharmacy earned discounts; and
2. Efforts to provide equal access to prescription drug, non-profit prices, for the non-profit Medicaid out-patient drug program.

What follows are Senator Harkin's questions and Secretary Sullivan's answers.

Senator Harkin & Secretary Sullivan
Question and Answer

1

MEDICAID DRUG REIMBURSEMENT

As I understand it, under HCFA's regulations, retail pharmacists would lose the discounts they receive from their wholesalers if a pharmacist participates in a Medicaid pharmacy program. While HCFA may view this policy as holding down Medicaid costs, I am informed there are doubts that this approach controls rising Medicaid drug prices. This regulatory issue is being litigated in the Fifth Circuit (State of Louisiana v. U.S. Department of Health and Human Services, 89-4566).

Question. Has HCFA given any consideration to imposing a moratorium on such regulatory efforts at least until the Fifth Circuit has determined the legality of such initiatives?

Answer. No, we have not. Unfortunately the characterization of this activity as an initiative is incorrect. HCFA policy regarding prescription drug payments under Medicaid is that the amount is determined by first establishing an Estimated Acquisition Cost (EAC) for drug products. The EAC must be the states' best estimate of the prices that pharmacies are generally and currently paying for drug products. Many studies and most information available on this subject show that the list prices for drug products-commonly known as Average Wholesale Prices (AWP) rarely, if ever, reflect the prices pharmacies actually pay. In fact, most information shows that the discount off AWP is usually between 10-20 percent.

Since 1976, our policy has been that AWP is not an acceptable measure of EAC. Most States have systems that determine EAC in such a manner that AWP is not used, or they apply a significant discount to AWP.

The State of Iowa is one such State that is not in compliance with these rules and thus, efforts are underway to bring them into compliance.

The case pending before the 5th Circuit has not prompted HCFA to cease any of these activities because that case is one where a state is challenging HCFA's authority to administer the Medicaid program in accordance with existing rules.

Question. What evidence is there that this regulatory approach has any impact on Medicaid drug costs?

Answer. We believe that the continued use of unmodified average wholesale price (AWP) as a state's estimated acquisition cost results in overpayments. In 1984 an Inspector General's report found that the AWP as the basis for determining drug product costs for purposes of prescription

Senator Harkin & Secretary Sullivar
Question and Answer

2

MEDICAID DRUG PRICES

Medicaid drug costs now exceed $3 billion annually. Prices for the same drug can vary widely among suppliers, and some hospitals and health maintenance organizations have been able to negotiate steep discounts for volume purchases.

Question. How many State Medicaid programs currently take advantage of group discount purchasing to save money on prescription drugs?

Answer. It is my understanding that 18 States have restricted drug formularies or lists of Medicaid approved drugs which may take advantage of group discount purchasing. It should also be noted that Kansas has the only Medicaid drug program which uses a competitive bidding process to obtain discount prescription drug prices.

Question. What can be done administratively to encourage States to save Medicaid funds through discount buying?

Answer. At the present time, unfortunately, very little. HCFA in the past has encouraged States to engage in volume purchasing for prescribed drugs because of the potential for significant savings. However, we have been unable to assist the States in overcoming their major problem of the refusal of drug manufacturers to submit bids. This is because HCFA has no direct relationship with drug manufacturers, since we match State expenditures for drugs and the States provide payment for the drugs through pharmacy providers.

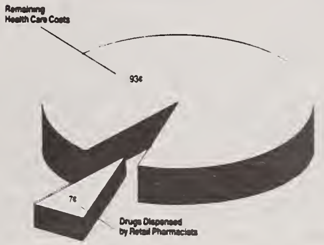
Question. Would you favor legislation to mandate that States establish programs to negotiate lower drug prices?

Answer. We would support States' efforts to negotiate lower prescription drug prices. In fact, we require State Medicaid programs to purchase drugs at an "estimated acquisition cost", a price below the "average wholesale price."

States have attempted to negotiate lower drug prices with drug manufacturers but, to date, have been largely unsuccessful. Legislation could help provide States leverage to obtain drugs for their Medicaid programs at a lower or discounted price.

WHAT DOES MEDICAID SPEND FOR PRESCRIPTION DRUGS?

Percent of Medicaid
Expenditures for Drugs



The Medicaid Dollar

Source: Health Care Financing Administration

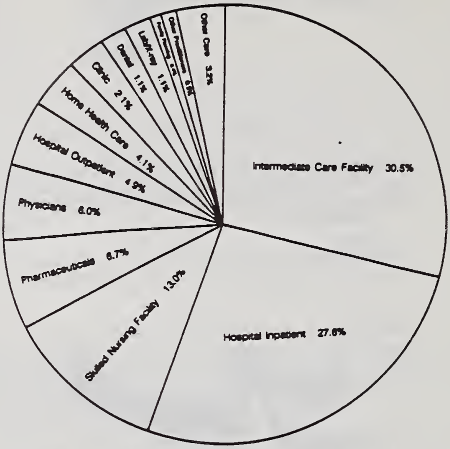
- Facts at a Glance, 1989, P.M.A., page 29

Equal Access

WHAT ABOUT THE PRESCRIPTION DRUGS PURCHASED BY THE OTHER COMPONENTS OF THE MEDICAID PROGRAM?

MEDICAL ASSISTANCE PROGRAM BENEFITS (TITLE XIX)
TOTAL U. S. VENDOR PAYMENTS BY TYPE OF SERVICE

1988



Other care includes early & periodic screening, rural health clinic services and miscellaneous other care.

	FY 1987	% Total	FY 1988	% Total
Intermediate Care Facility	$12,979,136,955	28.7	$13, 944,343,122	30.5
Hospital Inpatient	12,704,831,547	26 1	13,451,559,730	27.6
Skilled Nursing Facility	5,975,168,829	13.2	6,353,550,690	13.0
Pharmaceuticals	2,998,740,591	6.6	3,294,329,484	6.7
Physicians	2,779,075,398	5.9	2,952,942,359	6.0
Hospital Outpatient	2,226,110,933	4.9	2,413,028,723	4.9
Home Health Care	1,697,428,070	3.8	2,015,480,818	4.1
Clinic	955,475,921	2.1	1,105,212,592	2.2
Dental	541,382,054	1 2	577,365,685	1.1
Lab/X-ray	469,332,721	1.0	543,481,062	1.1
Family Planning	226,908,697	0 5	205,688,699	0.4
Other Practitioners	265,175,204	0 6	284,235,721	0.5
Other Care	1,350,053,320	3.0	1,568,897,340	3.2
TOTALS	$45,170,130,338		$48,710,157,836	

Above figures include Puerto Rico and the Virgin Islands.

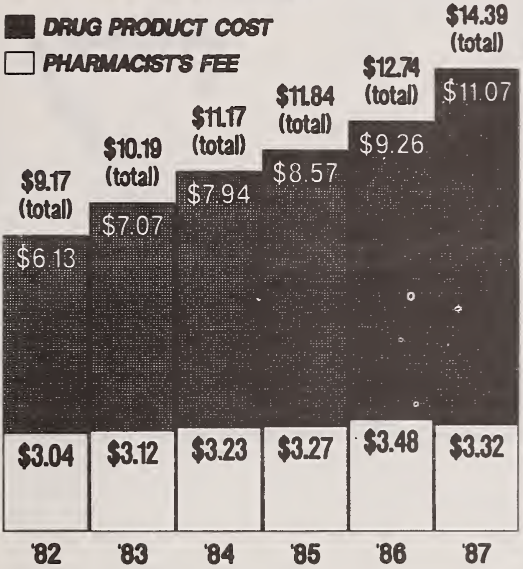
Other care includes: early and periodic screening, rural health clinic services and miscellaneous other care.

Pharmaceutical Benefits Under State Medical Assistance Programs,
National Pharmaceutical Council, September 1989

Office of General Coun
NARD

Cutting Reimbursement Hurts Pharmacies Without Affecting Drug Prices

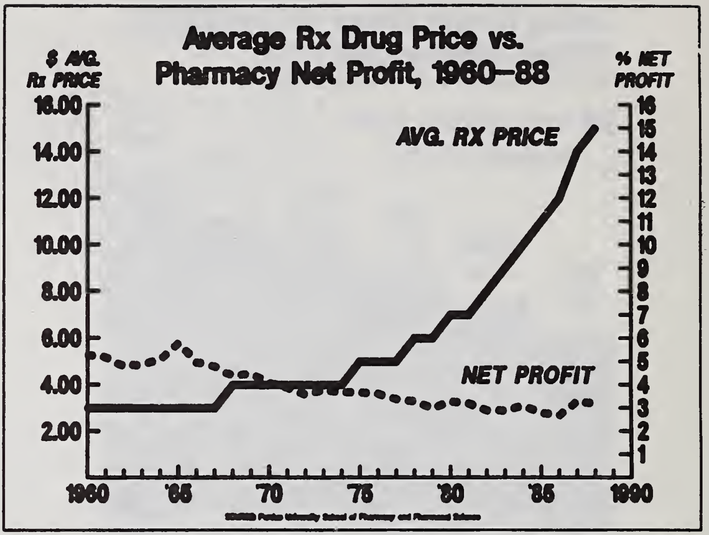
Medicaid Rx Drug Reimbursement Components, 1982–87



SOURCE: Compiled by the Pharmaceutical Economics Research Center, Purdue University, from data found in Benefits, Under State Medical Assistance Programs, Reston, VA: National Pharmaceutical Council, various years.

U.S. Senate Special Committee on Aging
"Prescription Drug Prices: Are We
Getting Our Money's Worth?"
August 1989

Office of General Counsel
NARD



U.S. Senate Special Committee on Aging
"Prescription Drug Prices: Are We Getting
Our Money's Worth?"
August 1989

PHARMACEUTICAL DIVERSION

EXHIBIT 1

PRODUCT ANALYSIS BY TIER PRICING

Product	AWP ($)	Contract ($)
Tylenol tabs., 325 mg., 1000	32.54	2.84
Proventil inhaler, each	9.18	2.95
Omnipen-N, inj., 1g., 10s	148.69	35.70
Velosof, 250 mg. caps., 100s	38.71	14.80/10
Lotrimin 1% cream, 15 g. each	5.27	.99
Garamycin, 80 mg./2 ml. inj.	84.50	10.20
Alupent tabs., 10 mg., 100s	12.22	2.99
Depo-medrol, 40 mg. inj.	4.95	2.30
Transderm Nitro, 2.5 mg.	28.70	.30
Nilstat Susp., bowel	13.84	1.78
K-Lor, 15 mg., 100	28.58	3.50
K-Tab, 10 mg., 100	10.44	.62
Kaon-ce tabs, 100	9.49	3.00

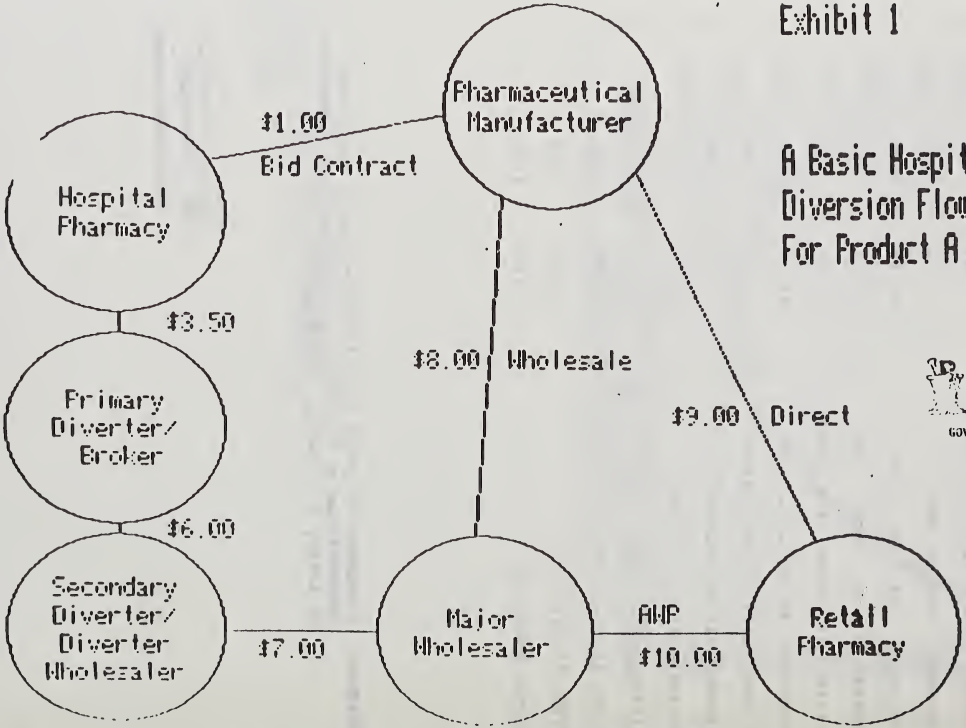
Reference: Statement of Eddie Ronald Burklow before the House Subcommittee on Oversight & Investigations, Committee on Energy & Commerce, September 19, 1985

The National Association
of Retail Druggists
GOVERNMENT AFFAIRS DEPARTMENT

Exhibit 1

A Basic Hospital-Type Diversion Flow Chart For Product A

Compliments of
The National Association
of Retail Druggists
GOVERNMENT AFFAIRS DEPARTMENT


Pharmaceutical Manufacturer
$1.00
Bid Contract
Hospital Pharmacy
$3.50
Primary Diverter/ Broker
$6.00
Secondary Diverter/ Diverter Wholesaler
$7.00
$8.00
Wholesale
Major Wholesaler
AWP
$10.00
$9.00
Direct
Retail Pharmacy

STATEMENT OF STEPHEN F. SIMS AND DAVID W. NELSON
BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE COMMITTEE ON ENERGY AND COMMERCE, July 10, 1985

99th Congress
1st Session

COMMITTEE PRINT

Committee
Print 99-R

DRUG DIVERSION

Prescription Drug Diversion and the American Consumer: What You Think You See May Not Be What You Get

A STAFF REPORT

BY THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

JUNE 1985

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1985

[illegible] O

Provided as a service by the National Association of Retail Druggists

Department arrested Mr. Moffett, who pled guilty to wholesale distribution of prescription drugs without a license. He was fined $100.00 and assessed $100.00 in court costs and a judgment fee of $5.00. Approximately 66,000 tablets of Tagamet and 124,500 tablets of Aldomet, whose combined value was about $68,000, were seized by Wayne County.[15] Neither the FDA nor the Tennessee state licensing board took any action against Jon Moffett or W. Richard Reeves, the owner of the nursing supply company. According to a spokesman for Merck, the manufacturer of Aldomet, the Canadian formulation includes yellow dye while the U.S. product does not. The dye could cause a reaction in patients with certain allergies, but a doctor would have no way to prevent this reaction because the drug was relabeled.

The Operation of the Diversion Market

The Florida case involving the bogus charities described above also revealed some significant information regarding the operation of the diversion market in the United States. As part of their case, the defendants called witnesses who testified that diversion was a standard practice and a time-honored method by which at least some pharmaceutical retailers obtain supplies. As indicated in the previous section, salesmen might sell to diverters to meet quota, to move an oversupply of a certain product, or for various other reasons that were approved or tolerated by the companies.

One witness, Robert Brewer, had been director of purchasing and distribution of pharmaceuticals for Revco Drug Stores, a large chain.[16] Mr. Brewer testified that between 1955 and 1957 Revco purchased

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[14] The FDA case record is retained in the Subcommittee's files. Details of the episode were also confirmed in interviews with the drug manufacturers concerned.

[15] _Id._

[16] Transcript, p. 3020.

about $150 million worth of pharmaceuticals, about twenty percent of which were from diverters, and that this was a standard way of conducting business during his employment with the company.[17] Mr. Brewer also said that Revco had established subsidiary companies which specialized in the purchase and resale of diverted pharmaceuticals,[18] and that periodic reports on the practice were submitted to the company's top management.[19]

When asked how pharmaceuticals entered the diversion market, Mr. Brewer identified nonprofit associations, hospitals, clinics and nursing homes as sources.[20] International Christian Relief in Washington, D.C. sold several million dollars worth of pharmaceuticals to Revco, he recalled.[21] While purchases from diverters were attractive because they gave Revco a price advantage against its competitors, such purchases raise questions as to the quality of the merchandise. Mr. Brewer testified that it made no difference to Revco where the initial diverters purchased the merchandise, as long as they were licensed. He added:[22]

> All the people that we dealt with were duly licensed under their state and if they were duly licensed under their state the product was legitimate. And that is what our main goal was: To make sure that everybody was licensed.

The problem, of course, is that possessing a state license -- which is quite easy to obtain -- is no guarantee of quality. The importer and primary distributors of the counterfeit Ovulen 21 birth control pills were all licensed. This is certainly not to say that companies like Revco would knowingly purchase substandard pharmaceuticals. Rather, the testimony of Mr. Brewer and others in the case illustrate the dilemma that continues to exist in the marketplace today: in reference to quality, what risks should a prudent businessman take in order to obtain goods at favorable prices? The apparent widespread practice of buying diverted goods raises the related question of what risks a businessman needs to take in order to remain competitive? These questions cannot be answered in this report, but should be carefully addressed in Subcommittee hearings.

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[17] Id., pp. 3021, 3025.
[18] Id., p. 3034.
[19] Id., p. 3035.
[20] Id., p. 3023.
[21] Id., pp. 3027-28.
[22] Id., pp. 3034-35.

In any event, Revco appears to have continued its practice of buying from diverters. In the case where pharmaceuticals were diverted back to the United States while allegedly on their way to Zaire, the goods ended up in Revco's possession in Tennessee. Revco reportedly advanced the funds to the diverters, including the firm operated by Soloman Richman, prior to the purchase of the merchandise from the manufacturer. In this regard, one other part of Mr. Brewer's testimony is instructive. The following is a line of questioning of Mr. Brewer by the prosecutor:[23]

> Q. Now, sir, had you known that ICR [International Christian Relief], Opus Christi or Church of God was making false representations to manufacturers to get those products would you then have purchased those products?
>
> A. I would have probably taken it up with our Counsel.
>
> Q. You would have taken it up with your Counsel?
>
> A. Yes. I think I would have, yes.
>
> Q. And you don't know what, if any--

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[23] Id., p. 3082.

A. We would have probably purchased the merchandise.

Stanley Kowitt, owner and president of S.K. Enterprises, which did business with the other defendants in the case as Majestic Sales Company and American Drug Brokers, testified that his firms sell diverted merchandise to many major drugstore chains in the United States, including Revco, Eckerd, Drug Fair, Rite-Aid, Adams and Thrifty.[24] Mr. Kowitt went on to confirm that pharmaceutical products are traded freely in the marketplace to diverters and that he had never attempted to conceal from his customers the fact that he was dealing in diverted products.[25] One problem with buying from diverters, even though they are licensed, is that the retailer really has no guarantee that the product is genuine or effective. Eckerd Corporation, for example, discovered it had counterfeit Ovulen 21 in Dallas, Texas and Largo, Florida.[26]

The Fort Lauderdale setting of the trial was somewhat ironic in that a number of pharmaceutical wholesalers that specialize in diverted goods are located in the vicinity. According to Stanley Kowitt, between twelve and fifteen such companies could be found within a thirty-minute ride of the courthouse.[27] Mr. Kowitt also supported the testimony of Robert Brewer that charities and nonprofit institutions were sources of diverted pharmaceuticals. Mr. Kowitt estimated that the value of products in the diversion market between 1975 and 1977 exceeded $100 million per year.[28]

Further testimony on diversion was presented by Marvin Sandler, vice president of Interstate Drug

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[24] Id., pp. 3307-8.

[25] Id.

[26] A list of Ovulen 21 seizures or recalls is retained in the Subcommittee's files.

[27] Transcript, p. 3310.

[28] Id., p. 3336.

Exchange of Plainview, New York. Subsequent to the testimony, Mr. Sandler's firm was identified as one of the three main distributors of the counterfeit Ovulen 21. Because the matter is an open criminal case, the Subcommittee staff has not questioned Interstate Drug about their acquisition and resale of the bogus pills. However, Mr. Sandler's testimony openly acknowledged that the company has been quite active in the diversion market for a number of years.[29]

Mr. Sandler testified that his company bought pharmaceuticals from sources overseas, including Mr. Richman's company. Mr. Sandler said that it did not "cause him any concern" that the merchandise was coming from overseas and that his company was able to pay less than the regular wholesale price.[30] Moreover, Mr. Sandler testified that he would never think to ask a supplier where they obtained their merchandise.[31]

Another witness, Gerald Rome, president of the H.L. Moore Drug Exchange of New Britain, Connecticut, said that the diversion market had existed throughout his twenty-three years of experience in the wholesale pharmaceutical industry.[32] Mr. Rome said his firm got calls on a daily basis by suppliers offering diverted merchandise.[33] Mr. Rome testified that he does not know where his suppliers get their merchandise, adding that he would never knowingly buy stolen goods.[34] But since no questions are asked, it is unlikely that Rome's company would know whether the goods were stolen or not. Mr. Rome also stated that it would be no concern of his if he were offered goods that were purchased based on the representation that they would be used for charitable purposes.[35] Thus, at least one diverter seems to be saying that stolen merchandise, if identified as such, would be rejected, but pharmaceuticals obtained through false representations or fraud are perfectly acceptable.

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[29] Id., pp. 3105-6.
[30] Id., p. 3103.
[31] Id., p. 3106.
[32] Id., p. 3142.
[33] Id., p. 3147.
[34] Id., p. 3176.
[35] Id., p. 3181.

A recent example of this is found in a criminal prosecution of five individuals by the U.S. Attorney for the Southern District of New York. On May 3, 1984, Jack Randell, president and sole shareholder of Audit Data Inc., was indicted as the prime mover of a scheme that defrauded pharmaceutical manufacturers of approximately $3,400,000. Randell and his co-conspirators purchased pharmaceuticals through the United Cancer Institute (UCI), a previously existing nonprofit cancer research body, for the alleged treatment of cancer patients at UCI medical clinics. Using the not-for-profit organization exemption to federal antitrust laws, discounts of up to eighty percent off regular wholesale price were obtained. No such clinics existed. Mr. Randell also conspired with Louis Garruto, manager of the pharmacy advisory group, procurement department of the New York City Health and Hospitals Corporation, a nonprofit organization, to purchase discounted pharmaceuticals for fictitious health care centers through the New York City organization. The pharmaceuticals were resold to wholesale and retail merchants. The schemes were carried out between June 1978 and May 1982.[36] The sales personnel of the pharmaceutical companies became suspicious when the volume of sales to Mr. Randell increased significantly. After a few months, a company would refuse to make discounted sales. Mr. Randell would then switch companies. During the period of the conspiracy, Mr. Randell purchased discounted products from no less than seventeen different drug companies.[37]

One of the principal purchasers of the diverted goods was Med Sales, a Hollywood, Florida wholesaler. Med Sales was one of the wholesale pharmaceutical companies that were known to deal in diverted merchandise, according to the testimony of Stanley Kowitt in the Miami bogus charity case.[38]

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[36] A copy of the indictment is retained in the Subcommittee's files.

[37] Phone call information from U.S. Attorney's Office, New York.

The Subcommittee staff has pieced together one example of how the counterfeit Ovulen 21 was quickly moved through the diversion market after its introduction into the United States. The initial source of the Ovulen is not known to the staff, who have avoided such inquiry because of the open criminal investigation. Nonetheless, the rapid chain of resales and the movement of goods from region to region provides an excellent illustration of the operation of the diversion market. Thirty three hundred and fifty one units of twenty-one tablet packages were acquired by American Medic Sales, Inc. of North Miami, Florida from an unknown source at an unknown price. The goods were sold on June 20, 1984 to Marchar Laboratories of Walnut, California for $3.00 per package plus half the profit of the future resale by Marchar. On about June 22, Marchar sold the entire lot to H & H Pharmaceuticals (d.b.a. Medicine Man Pharmacy) of Seattle, Washington, for $5.00 per package. Thus, half of the profit, or $1.00 per package, was remitted to American Medic Sales by Marchar. On June 28, H & H sold the goods to Harry's Pharmacy of Palos Heights, Illinois for $6.50 per package. The average wholesale price of the pills was about $11.50 to $12.00 per package. The counterfeit pills came to rest at Harry's Pharmacy, where about 1275 packages were apparently sold at retail. In November 1984, after the existence of the counterfeit pills was widely reported, Harry's returned the goods to H & H, which was about to return them to Marchar when the pills were seized by the FDA.

Another example of the daisy chain distribution typical of the counterfeit pills was described in a Newsday article.[39] Beginning with an unknown source, the Ovulen was sold by Lantor Corporation, a Miami, Florida distributor, to three Long Island firms:

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[38] Transcript, p. 3311.

[39] Newsday, December 10, 1984.

Interstate Drug Exchange, Interstate Cigar Corporation and Quality King Distributors. According to Newsday, none of the three major wholesalers or companies in the subsequent sales chain questioned the origin of the product despite the unusually low prices. In one chain, Interstate Drug sold the bogus pills to Ritchie Pharmaceutical of Glasgow, Kentucky for $4.75 per package, which resold them to Williams Generics in Memphis, Tennessee for $5.80. Williams Generics sold the Ovulen to retailers for $8.95, "30 percent cheaper than they could get it elsewhere," according to Louis Williams, the owner. One of Williams Generics' customers, Kansas City pharmacist Jim Kerr, sold the packages at retail for $11.50. A Searle spokesman said the suggested retail mark-up was $13.50. Newsday reported that the counterfeit pills were known to have been sold in eighteen states.

Nonprofit Institution Diversion

As indicated in a previous section, nonprofit institutions that have purchased pharmaceuticals beyond their needs have diverted the excess to the wholesale market for many years. Recently, however, and in the face of apparent prohibitions against resales by the Robinson-Patman Act (15 U.S.C. 13), the volume of merchandise and the number of diversions from nonprofit institutions appear to have increased dramatically.

This is not to say that the practice is new. Extensive hearings in 1967 and 1969 before the House Select Committee on Small Business provided a forum for complaints that failure to enforce the Robinson-Patman Act was unfairly damaging retail druggists. The Act, in a nutshell, would prohibit a drug manufacturer from discriminating in price between purchasers of the same drug where the effect will injure competition. But, beyond a series of defenses and other hurdles, the Act also confers an important exemption for purchases "for their own use" by hospitals and other charitable institutions "not operated for profit." (15 U.S.C. 13c). Under this exemption, drug manufacturers have consistently sold pharmaceuticals to nonprofit hospitals at substantially greater discounts than those offered to the wholesale and retail drug trade. Where the hospitals buy more than they need for their "own use," and sell the excess to distributors or other third parties passing along a portion of the original deep manufacturer discount, diversion (as this report defines it) results. Wholesale and retail pharmacists have argued for decades that this diversion injures competition because they cannot obtain or match these institutional discounts.

The legality of this activity -- and the responsibility of a drug distributor who induces the hospital to buy too much, or a manufacturer who knows or suspects the hospital is buying more than it needs -- rests in major part on application of the "own use" provision of Section 13c. The Supreme Court shed considerable light on this issue in Abbott Laboratories, Inc. v. Portland Retail Druggists Association, Inc., 425 U.S. 1 (1976). While there are many forms of hospital drug dispensing other than to hospital in-patients that still meet the hospital's "own use" test, the Court made clear that dispensing drugs to the man on the street with no present connection with the hospital or its pharmacy (other than to buy its drugs) is not covered by the statutory exemption. It would seem, therefore, that a hospital's bulk sale of excess drugs to a wholesaler for subsequent resale to other distributors would also not fall within the hospital's "own use" exemption. This would render the initial discount at which these drugs were purchased an illegal price discrimination.

It also seems that the extent of the "own use" exemption will vary with the changing nature of the health care industry in this country. Recently, a Federal appellate court in California ruled that a nonprofit health maintenance organization (HMO) had an extremely broad institutional function -- broader than that of the traditional hospital considered in the 1976 Portland Druggists case. This function legitimately included a "drug plan" which allowed any member to purchase drugs at little or no cost from the HMO pharmacy for an additional monthly charge. Modena v. Kaiser Foundation Health Plan, Inc., No. 83-5720, (9th Cir. October 2, 1984). The HMO's purchases from pharmaceutical companies at significant discounts were, therefore, protected under the "own use" exemption so long as the HMO pharmacy sold to members; sales to non-members were not protected.

An entire industry has sprung up whose sole purpose appears to be to solicit nonprofit hospitals to purchase excess pharmaceuticals using their special discount, which products are then immediately resold to the broker or wholesaler for ultimate resale to a retailer. The current head of the California Board of Pharmacy told the Subcommittee staff that it was his guess that hospital diversion was the leading source of products for the diversion market in his state.

The Subcommittee staff has identified companies in California, Texas and New Jersey that are making such solicitations. California companies appear to be the most active, and one has made presentations to hospital buying groups in the Chicago and Detroit areas, among others. There also appears to be a significant overlap in corporate officers between several of the California companies. The legal opinions supporting the practice seem to stem from one Los Angeles law firm.

One of the more active companies is Healthcare Marketing Services, Inc. (HMSI), a broker whose principals are Sam and Iris Grant of Encino, California. According to its literature, HMSI represents "a licensed wholesale pharmaceutical distributor in the State of California," but the name of the company is not listed. The company is apparently Marchar Laboratories of Walnut, California, which was found to have purchased and resold thirty five hundred and fifty one units of counterfeit Ovulen 21 in June 1984.[40] The literature offers the hospital "the ability to share in tremendous profits" by purchasing pharmaceuticals at the hospital discount price and immediately reselling them to HMSI. The hospital can receive an immediate payment of cost plus eighteen percent for handling and profit, or half the profit after resale by HMSI less twenty percent handling cost. The solicitation promises a profit for a one-hundred bed hospital of between $2,700 and $8,000 per month.[41]

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[40] See discussion in diversion section.

HMSI attached to its solicitation a December 6, 1984 legal opinion to Iris Grant from Arthur R. Chenen of the Los Angeles law firm of Hirschtick, Chenen and Cavanaugh. The opinion argues that HMSI's proposal is not a violation of the Robinson-Patman Act.[42] The Subcommittee staff asked the American Law Division of the Library of Congress to analyze Mr. Chenen's opinion. The analysis, prepared by Ms. Janice Rubin, raises very serious doubts about the legitimacy or validity of the Chenen opinion.[43]

A very similar program was offered to a hospital in Norfolk, Virginia and others in February 1985 by Associated Brokers and Consultants (ABC) of Granada Hills, California. ABC's literature mentions "a wholesale distributor" that may be Marchar, and specifically identifies Arthur Chenen as their attorney. The Executive Vice President of ABC is listed as Robert Fenton. This appears to be the same person who signed a very similar offer on behalf of Raif & Associates of San Francisco, California. Moreover, the Raif solicitation letter of January 9, 1985 lists a "cc" to A. Chenen, apparently the same Arthur Chenen who is identified as counsel to ABC and who prepared the legal opinion for HMSI.[44]

Another California company making similar offers to hospitals is Institutional Drug Corporation, Inc. of Mill Valley. Stephen Blechman signed a December 21, 1984 offer letter, and appears to be associated with Raif & Associates and Mr. Chenen.[45] Yet another Los Angeles area firm making solicitations on behalf of an unidentified "licensed wholesale pharmaceutical distributor in the State of California" is Drug World, Inc. The company is apparently under the ownership or direction of Gordon Iler, an attorney. Drug World is reported to have solicited a hospital in Nevada to participate in a resale scheme.[46]

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[41] A copy of the solicitation is printed as Appendix B.

[42] The opinion is printed as Appendix C.

[43] Ms. Rubin's opinion is printed as Appendix D.

[44] The information is retained in the Subcommittee's files.

[45] _Id._

A variation on this general theme is a program wherein the Summit Hospital Corporation proposed to purchase pharmaceuticals in its Texas hospitals for transfer to the Summit Care Corporation Pharmacy in Burbank, California. The plan was apparently initiated in the fall of 1984.[47] Two Summit Care Corporation hospitals were involved in a diversion program with Marchar Laboratories and Bergen Brunswig Company, one of the largest pharmaceutical wholesalers in California, in 1983. The companies were disciplined by the California Board of Pharmacy for furnishing drugs without proper delivery records or records of transfer.[48]

This by no means exhausts the list of California companies involved in soliciting nonprofit institutions for diversion plans. The staff has received more reports believed to be reliable, of such offers by other companies. But since the staff does not have copies of the written offers, or in some cases no written offer was made, the names of the companies will not be mentioned, pending further investigation.

A New Jersey firm, Wilco Trading Company, Inc. of Lakewood, has sent letters and made telephone calls to hospital pharmacies in attempts to purchase "excess pharmaceuticals." Like several other such firms, Wilco has its own toll free telephone number.[49]

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[46] Id.

[47] Id.

[48] Id.

[49] Id.

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*Legislative Defense Fund, Department of Government Affairs,
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STATEMENT OF THE NATIONAL GOVERNORS ASSOCIATION

Mr. Chairman, members of the committee, the National Governors' Association (NGA) appreciates the opportunity to submit these comments on behalf of the nation's Governors about Medicaid prescription drug proposals under consideration by Congress.

We thank Senator Pryor for bringing the difficulty states have had containing prescription prices to the forefront of public debate. For years, Medicaid programs have sought to bring escalating prescription drug prices under control. Before the introduction of S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990, only two states had been able to successfully negotiate better prescription drug prices with the drug manufacturers, and in those states, only on a very limited basis.

The introduction of S. 2605 has changed this situation considerably. It has brought the manufacturers to the bargaining table. Several drug manufacturers have now approached states with offers to provide discounts to state Medicaid programs. Currently 31 states have contracted with various drug manufacturers. Without your legislation, this quick and necessary progress would not have been possible.

The ability for states to negotiate better prescription drug prices is long overdue. State medical assistance plans should receive the same discounts that are available to the Department of Veterans' Affairs, hospitals, and health maintenance organizations.

Each year, financially strapped Medicaid programs face the challenge of keeping pace with increasing Medicaid expenditures caused by spiralling health-care costs. A recent survey conducted by the National Association of State Budget Officers (NASBO) revealed that in 1990, state Medicaid spending increased by 18.4 percent. Medicaid now consumes a record-breaking 12 percent of state spending, second only to secondary education.

Rising prescription drug prices can be blamed for some of this increase. It is estimated that over the past 10 years, drug prices rose by 152 percent. Roughly 97 percent of this increase is attributed to price inflation which is about three times the general rate of inflation. Only 3 percent is the result of increases in prescription drug use. This places Medicaid spending for prescription drugs higher than for physicians

The magnitude of the increases show clearly why states support the goals of the legislation before this committee.

Before addressing our concerns with the prescription drug proposals, however, it is important to note that NGA has little policy on this issue and our comments are, therefore, based on extensive discussions with states. It should be stressed that the Governors themselves have not taken a position on this issue. The states are now in the process of reviewing and evaluating S. 2605 and S. 3029, introduced by Senator Pryor last week. Until we receive their responses, we must reserve judgment on both bills.

We would like to share with you the most frequent comments and concerns raised by states on the proposals before the committee.

Although the states that have negotiated with the manufacturers are pleased with the agreements reached, NGA does not believe any one of the manufacturers' proposals is appropriate at the national level.

The proposals require states to open their drug formularies to cover all of the manufacturer's current and future products to guarantee the best price. A Federal program must not require open drug formularies. We are pleased that currently states have been able to negotiate the "best price" with manufacturers without covering all single source drugs. States must maintain the flexibility to deny coverage for specific drugs or categories of drugs.

In states with closed formularies, expanding the number of drugs a state must cover would increase state spending on prescription drugs. This would work counter to the proposal's goal to reduce Medicaid expenditures for prescription drugs. Once Medicaid savings are achieved, a state could choose to use the savings to expand the formulary, or target the resources where they are most needed.

States are concerned with the language in the manufacturers' proposals to eliminate the prior authorization mechanisms. Prior approval serves two important functions in the Medicaid program. It allows authorization for a drug not covered under the state formulary and enables states to provide, on a limited basis, high-cost prescription drugs it would not otherwise be able to afford. Prior authorization is an important mechanism to ensure appropriate and medically necessary utilization of drugs. States must maintain the flexibility to determine what drugs are covered by the Medicaid program to ensure program stability and to ensure that quality and appropriate care is provided.

States also believe a national proposal should guard against increases in the base prices that could eliminate the discounts achieved by the "best price" over time. This concern relates to the experience states have had purchasing infant formula provided through Women, Infants, and Children (WIG) program. After a few years of substantial rebates from the drug companies to the states, the companies producing the formula tried to push prices higher, eliminating the value of the rebates. This had a dramatic effect on the WIG program and threatened the states' ability to provide infant formula to its most deserving populations. We recommend that any national prescription drug proposal index price increases in some fashion to prevent this from happening under & prescription drug rebate program.

The states are very receptive to the concept, presented in the manufacturers' proposals, which places the responsibility for facilitating discounts on the manufacturers instead of the state. One primary problem states had with S. 2605 was that it penalized states for failing to successfully negotiate with the manufacturers. The incentive for the states to negotiate with the manufacturers in S. 2605 seemed somewhat misdirected when, over the years, states have made several attempts to negotiate with the drug companies. If the manufacturer refuses to negotiate with the state, it is the manufacturer that should be penalized, not the state.

States also are concerned by the requirement in S. 2605 that the state must cover a drug in each therapeutic class. This would require some states to open formularies to classes of drugs they have chosen not to cover. States also are concerned by how easily a physician could override a designated preferred drug. This would eliminate the states' ability to impose prior authorization.

Another concern with S. 2605 centers on the method proposed for reimbursing pharmacists. States are concerned that basing pharmacist reimbursement on the lesser of the actual charge for the drug or the 90th percentile of the actual charge would be inflationary and consume any savings obtained by the discounts. Establishing pharmacist reimbursement is in the purview of state government and should not be regulated at the Federal level. It is important to note that most states have laws that forbid pharmacists from using therapeutic substitutes for prescribed drugs.

It is our understanding that Senator Pryor's most recent proposal addresses a number of these concerns. And that it appropriately places the focus of the legislation on the drug manufacturers and their ability to provide the Medicaid program discounts. We are pleased to see these changes and have sent the bill out to the states for review.

However, since we have not had the opportunity to review the new bill In detail or to discuss it with the states, we would like to reserve final comment until that review occurs. We will provide additional written comments on S. 3029 before the record for this hearing closes on October 8, 1990.

We reiterate the states' support for the goals of the legislation under consideration today. The introduction of S. 2605 alone has significantly improved the states' ability to negotiate better prices with drug manufacturers. We thank Senator Pryor for this important progress. Without his leadership, the savings that over 30 states are receiving from drug manufacturers would not be possible.

As this legislation moves forward, we look forward to working with the Senator to develop a final product that achieves our mutual goal of containing spiralling prescription drug costs, ensuring access to needed medications, and maintaining quality care for the nation's most vulnerable populations.

Statement of the National Mental Health Association

This hearing, to examine drug reimbursement proposals for the Medicaid program, occurs at a critical time. The National Mental Health Association, Mental Health Law Project and National Association of State Mental Health Program Directors are united in our concern about the escalating cost of pharmaceutical drugs and the inability of people with mental illness to pay for them. People with mental illness, who depend on medications to improve their functioning, rely on the Medicaid program to obtain the treatment and medication they need. The spiraling cost of therapeutic drugs, combined with Medicaid's limited resources for drug reimbursement, threatens the well-being of many Americans with mental illness.

This dilemma is underscored by the current controversy surrounding Clozaril, which represents a major break-through for the treatment of schizophrenia. Between bureaucratic rules and private greed, Clozaril is now nearly inaccessible.

Caught in the middle are patients and their families who seek relief from the devastating impact of schizophrenia. Clozaril offers tremendous hope to thousands of individuals with schizophrenia whose illness has not responded to other psychotropic drugs. Clozaril would enable individuals now residing in institutions, not only to move out into the community, but to live normal social lives! Families and consumers of mental health services view Clozaril as a "miracle drug."

Yet the promise of Clozaril may never be realized for these individuals because of the drug's exorbitant cost. Clozaril's annual expense of nearly $9,000 is prohibitive for most Americans. Families are desperately scrambling to find ways to afford this "miracle drug" for their loved ones. However, at the current cost, families' life savings would be depleted in a few years. The frustration of knowing that the life of your child (or spouse) who is now disabled by mental illness could be revolutionized, if you only could access appropriate treatment, is agonizing.

A large percentage of individuals with schizophrenia who could be expected to respond to Clozaril depend on Medicaid for their health care needs. This is because they are disabled (often receiving Supplemental Security Income) or have very low incomes and high health care costs (medically needy).

Currently, all state Medicaid programs pay for general hospital acute care services for these individuals and for various community services. The need for expensive hospital acute care services could be reduced significantly if Clozaril use was more extensive. Yet, ironically, only 13 states pay for Clozaril treatment, a much more effective and cost-efficient therapeutic approach. Those states which do cover Clozaril have severely restricted access to the drug because of the high cost and limited state resources. Thus, even with both private and public insurance funds, most people with schizophrenia simply cannot obtain the treatment they desperately require at the price of $172 per week.

In addition to the high cost of Clozaril, the use of an exclusive patient monitoring system (Clozaril Patient Management System or CPMS) is also alarming. Since Clozaril is tied (or bundled) with an exclusive monitoring and distribution system, Medicaid programs cannot separate the cost of the drug from the cost of monitoring. Sandoz Pharmaceuticals, the manufacturer, has contracted with Caremark as the exclusive monitoring system to guard against the adverse (possibly lethal) side effect of agranulocytosis which may occur in an estimated one percent of people using Clozaril. Thus, access to Clozaril is limited to patients who participate in (and pay for) CPMS.

While careful patient monitoring is essential, the National Mental Health Association, Mental Health Law Project and National Association of State Mental Health Program Directors question the use of an exclusive monitoring system arranged by the pharmaceutical company, Sandoz. The main component of CPMS is monitoring patients' white blood cell counts to observe whether problems arise from the use of Clozaril. Yet taking white blood counts is a routine procedure which can occur at labs throughout the nation. Undoubtedly, comparable monitoring systems could be developed which are less costly than CPMS, likely leading to a reduction in the overall price of the drug. The U.S. Department of Veterans Affairs already has proposed a comparable alternative system for monitoring VA patients using Clozaril; however, Sandoz has rejected the VA's offer.

Sandoz has contended that comparable monitoring systems could not insure the level of patient safety offered by CPMS. However, even the Food and Drug Administration (FDA) has indicated that CPMS is not the only acceptable system for distributing Clozaril. In communication with Sandoz, the FDA requested that Sandoz change the label references to CPMS as "Clozaril's labeling allows the incorrect inference that the product's distribution and sale is only permissible under a system of services provided by a single, specific vendor." Instead, such label references must include "descriptions of the essential elements of an acceptable system" The FDA also explicitly says that a centralized registry of all patients who ever used Clozaril is *not* necessary for safe distribution of the drug. This concept of a national data base, another major component of CPMS, has been used by Sandoz to contest the feasibility of establishing other distribution systems apart from CPMS. Yet, the FDA stated it "would still consider Clozaril "safe for use" whether or not a centralized registry is maintained."

In addition, Sandoz has not provided government or industry representatives with a breakdown of costs associated with manufacturing the drug and running CPMS. As a result, observers are unable to assess the fairness of Clozaril's price or determine alternative ways of paying for the drug. Without this vital information, groups are left to assume that Sandoz is exploiting its medical break-through and earring profits at the expense of persons with debilitating mental illness. We have called on Sandoz to make Clozaril more accessible to the individuals who need it. Clozaril should be available, affordable and accessible to all persons who might benefit from the drug.

S. 3029, sponsored by Senator Pryor, would require drug companies to offer Medicaid their "best price." This is one approach to curb rising Medicaid costs and increase access to important drugs. Unfortunately, this step toward expanding the availability of drugs is worthless for those patients seeking Clozaril treatment; Clozaril would be excluded from coverage under the proposed legislation because drugs which are "bundled" with a patient monitoring system are exempt from the negotiation requirements.

Clozaril's omission from the list of cove red drugs, while perhaps well-intentioned, is a serious set-back for consumers who rely on Medicaid to pay for treatment. In fact, any suggestion to explicitly prohibit Medicaid reimbursement for drugs combined with patient monitoring systems is ill-founded. This attempt to discourage the development of bundled drugs by denying access for Medicaid patients primarily harms the patient. If the Federal Government wishes to deal with the issue of bundling, the FDA and other appropriate agencies should move in and revise their procedures and regulations to prohibit such practices. The issue of bundling should be addressed directly, not through the indirect route of Medicaid reimbursement.

We strongly urge that all Medicaid eligible individuals have access to Clozaril and an appropriate monitoring system. Clozaril should be treated as any other pharmaceutical drug under Medicaid. Some possible avenues to achieve this objective, including unbundling Clozaril from CPMS and/or granting the Secretary additional authority to negotiate with Sandoz directly about availability, follow in the remaining testimony and in the attached joint position statement from our three organizations.

The issue of availability and accessibility to Clozaril is considered paramount to the National Mental Health Association, Mental Health Law Project and National Association of State Mental Health Program Directors. If the Subcommittee ignores this grave concern when reviewing S. 3029, an important opportunity will have been lost. We call upon the Subcommittee to investigate and take action on the restrictive access to Clozaril for Medicaid beneficiaries. One approach might be for Congress to authorize the Secretaries of Health and Human Services and Veterans Affairs to designate appropriate agencies (for example, State Medicaid agencies) which are capable of monitoring Clozaril use within their jurisdiction. Consequently, Sandoz would be required to make Clozaril available to those designated agencies deemed suitable to serve as monitoring agencies. Thus, access to Clozaril could be increased for many more patients, including Medicaid eligible patients. We urge you to consider this proposal and the attached joint policy statement on Clozaril as you deliberate on Medicaid drug reimbursement proposals.

Immediate Congressional action is required if the people with mental illness are to benefit from medical advances and move out of institutions and be independent and productive citizens.

MENTAL HEALTH COALITION ON CLOZAPINE

Policy Statement

A COALITION OF MENTAL HEALTH ORGANIZATIONS, consisting of Mental Health Law Project, National Association of State Mental Health Program Directors and National Mental Health Association, FINDS:

- Sandoz Pharmaceuticals has released Clozaril/clozapine, an important new drug for the treatment of schizophrenia. Clozaril/clozapine is a medical breakthrough as it may be a life-enhancing treatment for 30% of the 200,000–300,000 individuals who have not improved with other psychotropic medications. Currently, Sandoz distributes Clozaril/clozapine exclusively through the Clozaril Patient Management System (CPMS).
- Clozaril/clozapine should be available, affordable and accessible to all persons who might benefit from the drug.
- Clozaril/clozapine should be distributed quickly in a manner which is ethical, assures the safety of persons using the drug and protects the values of medical practice.
- Research has revealed the existence of potential adverse side effects of Clozaril which can lead to death. Therefore it is essential that comprehensive patient management systems be in place which ensure that all recipients off the drug are carefully monitored on a consistent basis.
- Due to the current high price of Clozaril and its associated CPMS patient monitoring system, most individuals who might benefit from it do not have access to it.

Many states are unable to allocate the financial resources through Medicaid or direct appropriations necessary to pay for the costs of Clozapine.

Sandoz, by virtue of its unwillingness to reveal the costs of Clozapine as well as the associated CPMS, has made it impossible for the Federal and state governments, advocacy organizations and other interested parties to evaluate whether the established price is in fact reasonable.

Sandoz has also not been willing to consider monitoring systems comparable to that currently in existence under CPMS, even though allowed by FDA, and which are less costly than $172 per week. An example of such a system is one which has been developed by the U.S. Department of Veterans Affairs.

- CPMS interferes with the standard practice of medical care by allowing a pharmaceutical company to dictate treatment decisions because the CPMS case manager does not assess for other dangerous side effects of the drug.

CPMS case manager qualifications are not defined and may result in a non-professional making the decision to withdraw the drug.

The mandatory combining of this exclusive product with generic, non-patentable services from other companies may violate anti-trust laws.

THEREFORE, THE MENTAL HEALTH COALITION ON CLOZAPINE CALLS FOR:

- All individuals unable to afford the cost of Clozaril/clozapine and CPMS must have access to the drug through public systems (Medicaid, state and county mental health systems) and other public sources of funding.

In order to achieve this objective:

- Sandoz should provide information on the cost of Clozaril/clozapine without the associated costs of the CPMS.
- The cost of Clozaril/clozapine should be separated (unbundled) from the CPMS.
- Alternatives to the CPMS should be developed and accepted by Sandoz for patient monitoring.
- Congress should conduct hearings to examine the problems that have arisen in the distribution of Clozaril/clozapine and the possible implications for other drugs which may be produced in the future and to identity any further legislative or regulatory remedies that may be necessary to ameliorate the current situation and prevent future problems.

Statement of the National Multiple Sclerosis Society

Mr. Chairman and members of the Finance Subcommittee on Health for Families and the Uninsured, I am Nancy Holland, director of chapter and community services for the National Multiple Sclerosis Society, and a registered nurse with more than sixteen years experience in caring for people with multiple sclerosis. Thank you for this opportunity to present our concerns regarding S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990, S. 3029, the Medicaid Anti-discriminatory Drug Price and Patient Benefit Restoration Act, and the potential impact of therapeutic substitutions on people with MS.

Multiple sclerosis serves as a model for chronic, disabling conditions. While primary symptoms are neurologically based, multiple systems may be affected including urinary, respiratory and gastro-intestinal (bowel). Therefore, comments relative to MS can be presumed applicable in certain other chronic illnesses or disabilities.

MS symptoms vary widely among individuals and also fluctuate over time in each person. onset is generally during young adulthood, but with a near-normal life expectancy, thirty to forty years of disease duration can be anticipated. During this time, symptom relief and prevention of complications can have a profound impact upon quality of life and illness-relasted costs.

The proposed legislation would require substitution of drugs within a particular category, with the specific substitution dependent upon negotiations with various pharmaceutical companies. This is disadvantageous to people with multiple sclerosis since medical management may involve continuous manipulation of therapies to achieve optimal benefit and to accommodate the fluctuations in disease manifestations.

While various drugs with similar action may sometimes be prescribed sequentially until the desired effect is achieved, such drugs are not interchangeable due to disparate individual responses. Following are some examples of drugs within groups "anticipated to have the same effect," but *not* interchangeable in management of MS dysfunction. Substitution between these drugs is therefore contra indicated.

1. *Lioresal vs. Dantrium.* Both drugs reduce MS stypes of spasticity. However, Lioresal has been demonstrated effective at high doses without serious side effects (main side effect is drowsiness), while Dantrium has been shown to result in liver toxicity in many cases.
2. *Tricyclic anti-depressants.* While all drugs in this group are anti-depressants, individual medications are used for their nonepressive effects useful in managing several MS problems.

- Tofranil is used for its action to manage certain types of bladder dysfunction, even though it is also an anti-depressant.
- When an anti-depressant drug is required, Tofranil or Desyrel might be used, depending upon the type of bladder problem the person is experiencing. Therefore, these drugs are not interchangeable even though both are anti-depressants.
- Elavil, a different type of anti-depressant, is very effective in relieving specific kinds of pain associated with MS.

3. *Anticholinergics.* Certain types of MS bladder dysfunction are treated with drugs in this group, including Probanthine and Ditropan. There is usually a "trial-and-error" process with a particular drug or combination of drugs, and titrating of dosage based upon response. There is considerable variance in individual response to these drugs, and each one must be titrated to establish the most effective regimen. Thus, again, these drugs are not interchangeable.
4. *Dilantin vs. Tegretol.* Although these drugs are both anti-convulsants, Tegretol is the therapy of choice for MS nerve pain, while Dilantin does not have this same benefit.

These examples indicate the many ways in which therapeutic substitution is *not* appropriate for MS and can interfere with or even be harmful to patient management. only a doctor with close observation of the patient can determine appropriateness of any therapy or therapeutic substitutes. Such cannot be legislated or made automatic on pricing considerations.

We have two other concerns about the impact of S. 2605 and S. 3029. First, pharmacists would begin to collect or ask about the medical history of the customer. The pharmacist would need to know the diagnosis for which the prescription is written. This has the potential of compromising confidentiality. People with MS (and many other illnesses) often have reasons why they do not want to disclose their diagnosis—even to the pharmacist and/or anyone within earshot at the pharmacy. It is our belief that the specific nature of the diagnosis should remain between the patient and his or her physician.

Second, if a pharmacist is unable to reach a doctor to question a prescription, the bill would allow him to provide a portion of the prescription as written until the doctor is reached. The intent of obtaining a doctor's permission to use a less costly drug thus results in the patient having to return to the pharmacist to pick up the prescription. This in itself is a significant problem. With MS, it can be difficult for a person to get out and around, even to run basic errands. This may be because of fatigue, a common MS symptom, or the lack of personal care attendants, family support, etc. We feel that additional trips are an unfair burden to put on such a patient who, following the doctor's directions, has gone to fill a prescription to alleviate his symptoms.

The National Multiple Sclerosis Society obviously favors reduced Medicaid costs. It is our urgent concern that it not be accomplished at the expense of the health of people with multiple sclerosis.

House of Representatives,
Lansing, MI, June 7, 1990.

Hon. Donald W. Riegle, Jr.,
U.S. Senator,
105 Dirksen Senate Office Building,
Washington, DC.

Dear Senator Riegle: As a member of the House Appropriations Committee and serving on the Social Services Subcommittee, I would like to request your assistance in defeating S. 2605, a bill sponsored by Senator Pryor of Arkansas.

This legislation would mandate restrictions on medications for Medicaid patients, which mean the young and old alike, We, here in the Michigan Legislature, mandated inclusion of most major medications on the Medicaid drug formulary list so that our poor would not be denied access to needed medications.

While I feel Senator Pryor's intentions of reducing Medicaid prescription drug costs are good, I also feel it could have adverse effects on the recipients if we cannot deliver the level of service to meet their needs or what their physician prescribes. Further, I do not feel Michigan should have these mandates placed upon us when we have repeatedly rejected going to restrictive formularies. To say we cannot include most major medications on our Medicaid drug formulary list would be undermining our decisions and authority.

Your help in defeating Senator Pryor's bill would be greatly appreciated.

Sincerely,

RALPH OSTLING, *State Representative,*
103rd District

STATEMENT OF HON. SHELBY A. RHINEHART, TENNESSEE HOUSE OF REPRESENTATIVES

Thank you for inviting me here today. I know you are all working overtime trying to figure out how to keep the Medicaid program solvent. It's a problem we have been grappling with ourselves for the last few years.

My own experience has been relevant to this issue, I have been a member of the Tennessee House of Representatives for 24 years and have served as chairman of two of its committees: Commerce for two years and Fiscal Review for ten years. Of course, Medicaid is one of the big items in the State's budget that comes before the Fiscal Review committee. This year, it will be $1.16 billion. Drugs are about 8 percent of that, or $100.2 million, of which nearly 30 percent goes to pharmacy fees. For all their complaining, pharmacists have done pretty well by the Medicaid program.

I can say this because I am also a practicing pharmacist. I own and operate my own pharmacy in Spencer, Tennessee. It's a relatively small operation. We do about $300,000 worth of business a year. It's because of my legislative responsibilities, perhaps, that my views about Medicaid pharmacy reimbursements differ substantially from those you will hear from pharmacy organizations.

Basically, I think state governments should be left alone to work out their own arrangements with pharmaceutical companies. The Federal Government wants to save money on its Medicaid drug bill. But state governments want to save Medicaid dollars too. Last year, for example, Tennessee decided to reduce expenditures for Medicaid prescription drugs from $105 million to $95 million, and payments to pharmacists by another $10 million. Because of the 70-30 match, the Federal Government ended up saving $14 million and Tennessee $6 million.

Recently, Tennessee agreed in principal on a contract with Merck under which the company will give the state rebates in return for Tennessee's adding all of Merck's single-source drugs to its Medicaid formulary. The rebates are the difference between Merck's Federal depot price—which is the lowest price it charges anyone—and its direct price to pharmacies and wholesalers. We calculate that the saving will amount to something between $200,000 and $250,000 a year.

Actually, only a couple of Merck's drugs were not on the formulary, and we have already added them to show our good faith. For its part, Merck has begun rebating us back to July 1. The contract will run until July 1, 1991. Merck would have made it renewable for another year, but state contracts cannot be automatically renewable. So we'll have to go through it again next year. In fact, the only thing holding up the contract is red tape.

Tennessee is also in the early stages of negotiation on prices with three other major pharmaceutical companies: Burroughs-Wellcome, Glaxo and Upjohn. And I would not be surprised if we get still more offers. I have read that at least 11 pharmaceutical companies are making offers to as many as 41 states. From what I understand, these 11 companies account for over half of all Medicaid single-source prescription drug costs, so the savings to the program should be substantial.

As a state legislator, I'd much rather have states negotiate these contracts individually than to have to work under a Federal program. The Merck contract, for example, is straightforward and simple. Unlike some of the proposals before you, it doesn't set up a hugh bureaucracy to look over everyone's shoulder. As a pharmacist, I hate to have the government get into anything of this sort. I've never seen the government save money when they get into the retail business.

I'm not too impressed, either, with the arguments put forward by the pharmacy associations. They support S. 2605 because they expect to make money by changing the reimbursement formula. They're just fooling themselves. The government wants to see Medicaid costs go down, not redistribute Medicaid dollars from drug companies to pharmacists. Whatever break they may get initially, when the program doesn't work—and you can be sure it won't save money—the pharmacists' 30 percent will begin to look very tempting.

Another thing is, I don't think pharmacists are going to be too happy about having to call the doctor every time someone walks in with a prescription for a non-listed drug. Kansas has a program similar to Senator Pryor's and the pharmacists there don't like it one bit. Almost half the Medicaid prescriptions they have to fill are for non-covered brands. That's a lot of phone calls. Also, it's not ail that easy to reach Medicaid doctors. often they're parttimers, working the emergency rooms in public hospitals.

Let me recap. The proposals in front of you are so elaborate, you can be sure they are not going to save any money. The states are already achieving savings from negotiated contracts that open up their formularies. That's the correct way to go. You should let us in the state houses do our job. We know we have to save Medicaid dollars. When we do, Federal Medicaid expenditures will go down as well.

South Dakota Pharmaceutical Association,
Pierre, SD, September 20, 1990.

Hon. Tom Daschle,
U.S. Senate,
Washington, DC

Dear Senator Daschle: This week, September 17–19, I was in Washington, DC to attend a meeting of representatives of states affiliated with the American Pharmaceutical Association. During this meeting we received briefings on S. 3029, just recently introduced by Senator Pryor. I was able to attend the hearing on this legislation and S. 2605 that was held by the Senate Finance Subcommittee on Health for Families and the Uninsured. After the hearing, I met with Rima Cohen and discussed these pieces of legislation with her.

On behalf of the pharmacists of South Dakota would like to ask your continued support of Senator Pryor's efforts and for your sponsorship of S. 3029. In your letter to us on August 2, 1990, you referred to questions raised about therapeutic interchange provisions in S. 2605. This legislation contains several changes from S. 2605 and does not have provisions for therapeutic interchange.

Since Senator Pryor's first initiative, several drug manufacturers have offered rebate proposals to state Medicaid programs. These proposals are a step in the right direction, but we are convinced that they will not produce lasting savings to Medicaid programs. Voluntary proposals vary in requirements and state Medicaid Departments will have much duplicative paper work to complete. By controlling the discount, the manufacturer maintains an inordinate power in controlling the direction of a Medicaid program. There are no guarantees that a manufacturer will maintain a discount over a long period of time.

The rebate language of S. 3029 may surface in the budget reconciliation process and we need your strong support to make sure that other provisions will also be included to insure that recipients and participants in the Medicaid program will be well served. The following "quality of care improvements" are of great importance to pharmacists and should be considered along with the rebate provisions.

1. *Access to Prescription Drugs Expanded:* The bill will significantly expand Medicaid beneficiary access to a wide range of FDA-approved prescription drug products and biologicals. To insure that Medicaid beneficiaries have access to drug products, those drug products not subject to the discount can still be obtained if the physician obtains prior approval from the state Medicaid program. The bill insures that the final control over the drug product selected for the patient is retained with the patient's physician. *There are no provisions in this bill for therapeutic substitution or therapeutic interchange of drug products by pharmacists.*
2. *Reform of Prior Approval Programs:* To make prior approval programs more responsive to physicians needs, states can only operate these programs if they meet certain minimal standards. South Dakota currently does not require prior approval for drug products.
3. *Drug Utilization Review:* The bill establishes a comprehensive system of drug use review (DUR) that encourages pharmacists to counsel patients on the proper use of their medications and requires state medical assistance programs

to implement a program to avert inappropriate patterns of prescribing and dispensing of drug products. The South Dakota Pharmaceutical Association has advocated the use of DUR to the Department of Social Services and supports this concept. We do have reservations about language in the bill that makes it appear that the DUR programs would be physician based. More appropriate language would give the states the option to select pharmacist based programs or continue using those programs in place.

The following provisions of S. 3029 are very important to our pharmacists and should remain in any final legislation:

1. *Restoration For Pharmacy Reimbursement Cuts:* For approximately three years after enactment, some of the cuts that have been made in pharmacy reimbursement over the past decade are restored by setting aside 10% of the rebates received each year by the state for this purpose.
2. *Reformation of Medicaid Pharmacy Reimbursement System:* The bill would effect reforms in the current pharmacy reimbursement system. After the three year pharmacy restoration expires (as described above), states would be required to update pharmacy dispensing fees each year based on the results of an annual study.

We appreciate your past support of pharmacy initiatives and hope that you will be able to assist us on this important issue.

Sincerely,

GALEN JORDRE, R.PH., *Secretary*

STATEMENT OF THE STATE MEDICAID DIRECTOR'S ASSOCIATION OF THE AMERICAN PUBLIC WELFARE ASSOCIATION

The State Medicaid Directors' Association (SMDA) of the American Public Welfare Association, appreciates the opportunity to comment on the various Medicaid prescription drug negotiation proposals under consideration by Congress and those offered by various pharmaceutical manufacturers. This testimony will highlight the activities of the SMDA in the area of pharmaceutical cost containment, the general preferences of Medicaid agencies, our concerns with some of the industry proposals, and some issues that we believe Congress should carefully consider in development of any drug pricing legislation.

The SMDA represents State Medicaid agencies in the 50 states, the District of Columbia and the territories. The American Public Welfare Association, of which SMDA is an affiliate organization, represents state and local human service administrators across the country and has other affiliates representing various components of state human service agencies. In addition, APWA represents some 4,000 individual members.

The SMDA appreciates the growing Congressional interest in the issue of the cost of Medicaid prescription drug programs. We would especially like to thank Senator David Pryor for taking the initiative to bring the subject to the forefront with his legislation S. 2605 and most recently S. 3029. We would also like to express our appreciation to Senator Riegle for holding this hearing on this very important subject. State Medicaid Directors have found that just the fact of growing congressional interest in the subject has facilitated rapid change and forward movement among pharmaceutical manufacturers. The Federal focus has created new avenues to negotiations from which several state programs are already benefiting. While much has occurred, we are certain that even more significant changes can be accomplished.

State Medicaid agencies have been concerned about the impact of increasing prescription drug costs on the overall program. A number of states began to look at innovative strategies to contain costs by developing ways to negotiate with manufacturers and wholesalers for price or volume discounts. The Kansas and Texas models may be the most well known to members of this Subcommittee. As more states began to look at taking action, and as those states that had developed innovative strategies met with minimal success due to industry opposition, the SMDA began discussions about possible strategies for multi-state action. Until recently, individual state agencies have generally not had sufficient leverage to bring manufacturers to the negotiating table. Unilateral action by state agencies was proving very difficult. Two years ago, the SMDA formed a Drug Reimbursement Subcommittee to explore state agency interest in pursuing multi-state action on drug negotiating.

To date, two surveys of state Medicaid agencies have been conducted. Both surveys indicated a high degree of interest among states for developing a drug bidding program. The surveys indicated a preference for the option to develop multi-state programs as opposed to simply the development of a national drug purchasing group. It should be noted that the surveys were conducted in a period prior to when drug manufacturers began offering discounts to individual states and at a time when states were feeling they had insufficient leverage. However, it is instructive to note that a multi-state option was sought because it could allow the greatest individual state flexibility with regard to: purchasing procedures; MMIS systems design/modifications; and the existence and composition of state formularies.

With regard to formularies, the surveys indicated that states believe a drug bidding program can be effective in the absence of a restricted formulary. While a restrictive formulary is generally viewed as more effective in the context of drug bidding, an unrestricted program would require a great deal of prescriber and dispenser education, and possibly incentives for the dispensers and/or prescribers. Allowance of therapeutic equivalence was viewed by survey respondents as a requisite for open formulary states in a bidding program.

Finally, the survey indicated that in order for any program to be worthwhile, the state should net a savings of 5% to 10% over any increased administrative costs in order to participate.

With state sentiment emerging, the SMDA Subcommittee has begun developing plans to move forward on a multi-state bidding program.

State agencies believe the manufacturer proposals currently under discussion in many states represent significant breakthroughs in terms of prescription drug cost containment. While SMDA believes these proposals, and manufacturer willingness to negotiate, has been a long time in arriving, state agencies are very pleased that several have begun to do so. While many states are considering the various proposals and others have signed agreements with manufacturers, the acceptability of the proposals varies from state to state depending on specifications of the individual state drug program.

In very general terms, state agencies have a few common concerns with different aspects of the proposals. Many states are very resistant to the idea of opening up current formularies. Current manufacturer proposals would, in some cases, require states to accept current and future products of a specific manufacturer in exchange for a guarantee of a best price on each. There is considerable uncertainty about the efficacy or therapeutic value of future drugs especially when compared therapeutically to other drugs, which raises concerns in formulary states. Other proposals call simply for open formularies, the costs of which could easily mitigate or eliminate any savings accrued from discounts or rebates on specific products. Some of the proposals specifically target elimination of prior authorization mechanisms. This procedure means either a method by which a prescriber can authorize a drug not covered by a formulary (an exception process) or a method by which a high cost drug covered by a formulary can be authorized for use in certain cases. Prior authorization may be used for specific drugs which may be utilized inappropriately, almost as a prospective drug utilization review. This mechanism is in place to ensure appropriate and medically necessary utilization. States that employ prior authorization are reluctant to forego it, especially when the future costs of the drug program and utilization are not well known or anticipated. Not all states necessarily share these concerns, depending on their specific program. However, even states without prior authorization may question the wisdom of foreclosing on future options.

Another general concern with the best-price and straight discount manufacturer proposals is the possibility of general price increases over time. There is nothing in any of the proposals to prevent price increases which would raise the base price over time and perhaps serve to both the manufacturer revenue loss and the effect on Medicaid savings.

The SMDA believes that there is room for greater movement on the part of manufacturers given that Medicaid nationally constitutes some 13% of prescription drug sales. Medicaid is funded by the taxpayers to finance care for the neediest citizens. It is time for manufacturers to come forward with significant and lasting price discounts that allow state programs to realize actual and significant savings so that ever scarcer health dollars can go further to serve more people.

The State Medicaid Directors' Association would like to request consideration of some broad concepts with respect to any proposal that may be considered, or any compromise that is yet to be fashioned by Congress.

In general, the SMDA believes that the appropriate focus of any legislation concerning drug price negotiations should lay the emphasis on the manufacturers. Until Senator Pryor's most recent proposal, the onus of negotiation and program operability has been on state Medicaid agencies. Many sticks and carrots have been considered for Medicaid, few for manufacturers. Drug price increases are simply beyond the control of a state agency, therefore a system of incentives and sanctions for making the whole bidding process work should not be structured around the state program. State agencies have demonstrated their willingness to make the concept work, well in advance of Congressional action. Failure to create change cannot appropriately be attributed to state agency shortcomings or lack of desire. Senator Pryor's most recent proposal appropriately changes the legislative focus which is necessary to ensure success.

Any proposal should provide for state flexibility. This flexibility will be of paramount importance for realizing savings. Most states, even in the most flexible program, would need to make administrative changes which will inevitably cost money. However, it is important that states administrative changes and costs so that there can be net savings. There can be considerable cost associated with start-up and continued operation of certain audit functions, systems changes, changes in procurement/purchasing policies and procedures, and changes in formulary. For these reasons, any program should be as flexible as possible so that states, or groups of states, can tailor negotiations and agreements so as to minimize administrative changes and associated costs, and thereby realize net savings. In resource-tight times such as these, it will be extremely difficult for states to begin a new process that will, in fact, cost more than the current program. Fiscal realities are such that this is simply not possible in some states. For some states, increased costs in one area of Medicaid will simply result in spending reductions in other areas: services, reimbursement and/or coverage.

Given these fiscal realities, it is very important that states not be required to open up their formularies such that more funds will be required. SMDA agrees with the Senator's intent of improved access. However, some states have already made deliberative judgments on issues of efficacy, cost, access to drugs, and general access within the context of the overall program. These are decisions that states are not necessarily in a fiscal position to change at this point in time. Many state programs are looking at substantial deficits that will require cuts from this fiscal year's Medicaid spending. Coupled with the prospect of further mandates and Federal cost-shift to states to reduce the deficit, many programs and their clients would be severely affected. We need right now to bring the cost of the prescription drug aspect of the program under control, using methods that make sense and do not jeopardize current levels of access. Expanding pharmaceutical access should be Jeff to the state to determine after the amount of savings realized can be accurately assessed. States may choose to invest savings in expansion of the number of covered prescriptions, rather than opening up the formulary. These are decisions best left to each state, which would consider a host of factors such as composition of the current formulary and the costs associated with an open formulary, the need and cost of increasing the number of prescriptions covered in a month all against the amount of savings realized under a new program. SMDA urges your serious consideration of this issue in particular. State agencies are still reviewing the most recent bill from Senator Pryor, S. 3029, so our comments on the specific provisions are preliminary. It appears the bill would go far in ensuring that unnecessary product cost increases will not occur over time, and in guaranteeing a minimum rebate amount. State agencies also appreciate the new focus on the manufacturers as expressed in the proposal.

Our preliminary review of the proposal, however, does raise a few general concerns. The administrative requirements of the bill will likely increase costs, reducing any savings to be realized through rebates. Such administrative costs include switching to standardized formats for reporting to both the Secretary and the manufacturers. It appears that states will have to use the national drug code, which is not currently used by all states and will result in new costs for those states. There will also be on-going costs associated with funding a State Drug Use Review Board to carry out the activities specified in the bill. In general, the Drug Utilization Review envisioned by the bill will result in higher administrative costs. We appreciate the enhanced Federal funding for many of the activities in the bill, but it must be acknowledged that these costs could be substantial and many of the costs will continue beyond the period of enhanced funding. There is also concern about how the enhanced funding will fare in any action to reduce Federal spending; Medicaid enhanced funding has been a target of budget reduction repeatedly over the years.

To restate an issue raised earlier, we are deeply concerned about the costs of open formularies. The bill appears to require coverage of all drugs for which there are rebates. The arguments will not be repeated here again, suffice it to say that the costs of such will be substantial in some states. The SMDA is concerned about the open formulary requirements coupled with the exception process (prior approval) outlined in the bill. It appears the exception process may provide a means by which a manufacturer does not have to provide a rebate but the drug would still be covered if the physician seeks prior approval and the drug may be medically indicated. There is also a concern about the costs and feasibility of the prior approval process outlined in the bill, and some concern about the impact of requiring immediate approval upon request especially when the prior approval mechanism is designed to ensure appropriate utilization. We believe there is a middle ground for compromise on this issue so that a process can be designed which accommodates Congressional intent and state concerns.

State agencies are concerned about the lump sum payments to pharmacists and do not agree that "draconian" cuts have been inflicted upon pharmacists through the Medicaid program. We do not have evidence of "access" problems with pharmacies. Indeed, the proposal seeks to assure " . . . that pharmaceutical services **continue** to be widely available . . . " (emphasis added).

Likewise, there is concern about annual and costly surveys to determine the correct price for dispensing fees. Again, it is not clear, given pharmacist participation, that states are far from the mark in determining dispensing fees. We do agree that the drug utilization review conducted by pharmacists will cost money—new computer systems and toll free phone lines—but state agencies should have the latitude to make appropriate reimburse using criteria they determine are important. The annual survey and fee adjustments seem to ignore the role of market forces. There is also concern about how a "reasonable effort" on the part of the pharmacist to conduct drug utilization review will be defined. Finally, there is concern that no reductions could be made for ingredient costs for a specified period under the bill. States are obtaining and utilizing better data to estimate pharmacist acquisition costs and should be free to use this data and reimburse ingredient costs based on costs to pharmacists. This is a separate issue from the dispensing fee. The bill's prohibition on exploring avenues of rational savings could undermine further savings in the program—savings that are based on reimbursing acquisition costs of the pharmacists.

Again, the comments on S. 3029 are preliminary and are based on comments from those states who have been able to review the bill and provide feedback in the very short time since introduction of the bill on September 12th. We appreciate Congressional interest in this issue and the continued efforts of Senator Pryor to reduce Medicaid prescription drugs expenditures.

State Medicaid agencies have followed congressional discussion on this issue with avid interest and have a great deal of hope for the outcome of your deliberations. State agencies, individually and through the APWA, are ready to provide any information you may need as the process continues and would like to continue to be involved the discussion as it proceeds.

Thank you for this opportunity to commit.

STATEMENT OF THE TEXAS HEART INSTITUTE

On behalf of the Texas Heart Institute, I am pleased to submit testimony for the Record of hearings held by the Senate Finance Committee Subcommittee on Health for the Family and the Uninsured regarding Senate Bill 2605, a fiscal year 1990–91 budget proposal by the Office of Management and Budget,—all pertaining to the Medicaid prescription drug program.

I am the Chief Executive Officer of the Texas Heart Institute, located in Houston. The name of our institution has become synonymous with quality health care. Each year more than ———— heart transplants, ———— by-pass surgeries, and ———— other procedures are performed at the Texas Heart Institute. Led by Dr. Denton Cooley, our physicians, staff and facility are at the forefront in the battle to control heart disease and associated ailments.

We are strongly protective of our system because it permits us to provide the highest quality of health care, and are thus very concerned whenever we learn of proposed legislation that would interfere with it. We believe the Pryor bill and the OMB measure would, if enacted, cause far more problems than either would solve. In addition, we have serious doubts that enactment of either measure would reduce Medicaid costs—in fact, it seems likely that both proposals would add to Medicaid expenditures. On the other hand, there are alternatives which would afford real savings without denying patients access to appropriate medicine or causing any of the problems likely to be created by the Pryor and OMB proposals.

Several of the major pharmaceutical manufacturing companies have recently begun offering their products to Medicaid at discount prices—ranging from a percentage of their current market prices to prices equal to the lowest charged any purchaser in America. These offers *could* result in real and immediate savings, not the soft estimate of savings set forth in the Pryor and OMB proposals. Note, though, my use of the word *could* when I refer to savings from industry proposals.

To the extent that patients are denied access to appropriate drugs, the purchase of avoidable but far more expensive services will become necessary. Trying to establish Medicaid prescription drug formularies like those used in some hospitals and Health Maintenance Organizations has been tried by Medicaid officials for years. Fortunately for the taxpayer, most states, like my own state of Texas, have learned that what works in the controlled environment of a hospital or an HMO cannot necessarily be extrapolated to the broad, public environment of Medicaid. In fact, no less an authority than the American Society of Hospital Pharmacists recently pointed out the OMB:

> "A formulary system involves more than the creation of a drug list. The OMB proposal to establish a national formulary for use by state Medicaid programs for therapeutic substitution does not accurately reflect the concept of a formulary system, whereby the medical staff of an institution, working through a pharmacy and therapeutics committee, evaluates, appraises, and selects from the numerous available drug entities drug products that are considered most useful in patient care. It is that interprofessional decision making, and the related general drug use policies that are developed in formulary systems that account for the real difference in terms of cost control."

Restrictive formularies, as the structures for limiting access of patients to more expensive medication are called, seem to be based on one or both of two premises:

- Cheaper drugs are "good enough" for Medicaid patients, who, after all, have little or no voice in politics.
- Bureaucrats know better than physicians what drugs to prescribe.

Neither premise seems sufficiently serious to warrant the attention of legislators, yet restrictive formularies are at the very heart of both the OMB and Pryor proposals. Even worse, these wasteful gimmicks could—if you are not very careful in your deliberations—become the end product of the proposals of the pharmaceutical companies to sell to Medicaid at discounts.

You see, only when all drugs are made available can drug therapy be truly effective. And without effective drug therapy you stimulate increased demands for emergency service, intensive care, hospitalizations, medical testing, surgery and other procedures which quickly wipe out any savings that can be realized from cutting the amount spent on medicine. The proposals of the pharmaceutical companies must not become the basis for restrictive formularies, composed only of those drugs for which Medicaid officials elect to negotiate.

Thus, the best alternative is one that *would not* deny access to any medication, so long as *all* medicines are made available to Medicaid at discount prices. Surely the writing of legislation that would establish and enforce such a program would be possible without extremely complex provisions of S. 2605 or the extraneous and troubling aspects of both the Pryor bill and the OMB proposal.

The major points of this alternate proposal are:

- Require Medicaid to make all FDA approved prescription drugs available to Medicaid patients, provided their manufacturers will sell them to Medicaid at a discount established in the legislation.
- Prohibit anyone from interfering with the physician in his prescribing of drugs for Medicaid patients.

Since some pharmaceutical manufacturers are already offering to sell to Medicaid at discount prices, it seems likely that others would follow. Truly cost effective as well as more efficient drug therapy, at great and real savings to taxpayers, can thus be achieved. Unless there are motives other than cost cutting in the OMB proposal, the Budget Office should quickly embrace the alternative outlined above.

On the other hand, Senator Pryor has said that his bill is intended to go further than simply reducing spending for Medicaid prescription drugs. His proposal has the additional intent of adding to the income of retail pharmacists. In an analysis of the Pryor bill by the Department of Health and Human Services of the State of Texas, the senator's intent to aid retail pharmacists was described as a bill that would "rob Peter to overpay Paul." [1] In other words, savings generated through discount purchasing from pharmaceutical manufacturers would be transferred to retail pharmacists.

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[1] 1. Memorandum, Subject: *Senate Bill 2605. Pharmaceutical Access and Prudent Purchasing Act of 1990,* Texas Department of Human Services, June 1, 1990

This special interest legislation would change the method by which the State of Texas and the majority of other states recompense pharmacists. Most states follow Federal guidelines, basing payments on Estimated Acquisition Cost plus a small percentage. Like Texas, most states also put a cap on the amount pharmacists are paid in dispensing fees. The Pryor bill would make all states recompense pharmacists much nearer to the Average Wholesale Price level, and remove caps on dispensing fees. Analysis by the Texas Medicaid office estimates that such changes would add $14.5 million annually to its payments for prescription drugs—none of which would go for medicines. And to make matters doubly irritating, states that have followed the Federal guidelines will be penalized, while states that have ignored them will be rewarded.

It seems obvious that a second alternative guaranteed to produce immediate, real world, countable savings would:

- Require all states receiving-Federal matching funds for Medicaid prescription drugs to follow existing-Federal guidelines for comprising pharmacists, and to establish a maximum amount for the pharmacist's professional dispensing fee.

Now, I should like to briefly discuss the Pryor bill and the OMB proposals, explaining why the Texas Heart Institute finds them so objectionable as to urge that they be quickly dismissed from further consideration.

Aside from the fact that both proposals would profoundly change an important public policy, possibly without benefit of hearings by Congressional committees charged with such matters, we find a single element common to both to be most troubling. Completely missing from either proposal is any thought of maintaining a high level of quality in prescription drug therapy for Medicaid patients—therapy that when properly administered can prevent heart attacks, hospitalization, and other drastic procedures. Instead of helping Medicaid recipients, the Pryor bill and the OMB proposal would be seriously injurious to them. Claims of Pryor proponents that the measures would broaden coverage by extending it to all therapeutic categories are simply spurious. No good will be accomplished by making a drug available if it is the only choice, it will not work, and might indeed be harmful to the patient.

Stripped of rhetoric, the Prior bill and the OMB proposal both would create restrictive formularies plus structures intended to make certain that they are followed by physicians. As set forth in S. 2605 and by the OMB, these formularies must surely be the most severe and most dangerous of any such contrivances yet conceptualized. Cloaked in different terminology, each proposal would limit Medicaid patients to the cheapest prescription drug in each therapeutic category.

Each proposed measure also calls for therapeutic substitution—switching by a pharmacist of a doctor's prescription to a cheaper drug included on the formulary. That the cheaper drug will often be of a totally different chemical formulation than the one the doctor prescribed is a foregone conclusion. The OMB proposal would not even require the pharmacist who makes the switch in medications to tell the doctor or the patient about it.

The Pryor bill attempts to achieve the same end but without the straight forward honesty of the OMB. Instead, S. 2605 would attempt to either wear doctors down or intimate them into going along with therapeutic substitution. The Texas Heart Institute is compelled to join the American Medical Association, the American heart Association, and the College of Cardiology in condemning therapeutic substitution because its use will produce terrible side effects including death.

Both bills will result in the increased hospitalization of patients, and already hospitals are struggling to absorb much of the cost of caring for Medicaid patients. During the past year alone, costs to one Houston hospital for Medicaid admissions exceeded Medicaid compensation by approximately $42 million. There is a limit to how much of such costs can be passed on to private patients and insurance companies. The failure of many rural hospitals is already a national disgrace, in part attributable to seriously deficient Medicaid compensation. Urban hospitals such as ours are probably at the limits in absorbing Medicaid losses. If they were not already so dangerous to patients, the Pryor and OMB proposals would still be dangerous to hospital solvency.

Aspects of the measures that are perhaps the most disturbing are those that would add enormously to pressures on our physicians—who, as you can imagine from the statistics that I presented earlier in this testimony, already have little or no time to call their own. Both bills would greatly broaden the liability of physicians and increase the cost of malpractice insurance. For those reasons alone, both measures would encourage physicians to stop seeing Medicaid patients. But there is more—there are provisions in the Pryor bill that are not only gratuitously insulting to the physicians, but which would establish a sort of police state environment in which they would be expected to work.

Try to picture if you will the spectacle of such a distinguished physician as Denton Cooley having to defend his prescriptions to a neighborhood pharmacist—perhaps right out of school. Imagine him having to justify a prescription by handwriting on it that it is medically necessary; or having to handwrite in the patient's record that he had prescribed a medicine that was medically necessary. Finally, do you really want a Denton Cooley subjected to a tyrannical review system replete with phone calls, letters, and visits from regulators making certain that he was not providing "medically unnecessary care?" These are requirements of the Pryor bill—there are others equally obnoxious and equally unnecessary, but I feel confident that I need draw no further word pictures for you.

In summary, both the Pryor bill and the OMB proposal would, if enacted, add to the overall costs of Medicaid through the stimulation of demand for services that efficient drug therapy would avoid. The Pryor bill would take an additional bite to of the taxpayer's pocket and give it to retail pharmacists. Both measures would throw more people into our hospitals, already struggling to overcome inadequate Medicaid compensation. And both proposals would be seriously damaging to physicians. The Pryor bill would even subject them to continual harassment of regulators looking to root out "medically unnecessary care." There are sound and economical alternatives to the OMB proposal and to S. 2605.

It is my strongest recommendation that both the Pryor bill and the OMB proposal be speedily discarded, and that deliberations over serious alternatives such as I have proposed by referred to the appropriate House and Senate health committees. Above all, these issues should not be resolved in a budget compromise.

Thank you.

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